

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, 2019.
- 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 of 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



If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange 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, 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 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

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

YES

NO



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.

The aggregate market value of Common Shares held by non-affiliates as of March 31, 2019 was \$743,730,984 based on a closing sale price of \$17.61 per share on March 31, 2019. As of October 31, 2019, 42,741,721 no par value Common Shares were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2020 Annual Meeting of Shareholders, which will be filed within one hundred and twenty days of the fiscal year ended September 30, 2019 (2020 Proxy Statement), are incorporated by reference into Part III of this report to the extent described herein.

MERIDIAN BIOSCIENCE, INC.
INDEX TO ANNUAL REPORT
ON FORM 10-K

Part I	Page
Item 1 Business	4
Item 1A Risk Factors.....	11
Item 1B Unresolved Staff Comments	20
Item 2 Properties	21
Item 3 Legal Proceedings	21
Item 4 Mine Safety Disclosures	22
 Part II	
Item 5 Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.....	22
Item 6 Selected Financial Data	24
Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations	24
Item 7A Quantitative and Qualitative Disclosures about Market Risk	33
Item 8 Financial Statements and Supplementary Data	34
Item 9 Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	68
Item 9A Controls and Procedures	68
Item 9B Other Information	68
 Part III	
Item 10 Directors, Executive Officers and Corporate Governance	69
Item 11 Executive Compensation.....	69
Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.....	69
Item 13 Certain Relationships and Related Transactions, and Director Independence	69
Item 14 Principal Accountant Fees and Services	69
 Item 15 Exhibits and Financial Statement Schedules.....	 70
Item 16 Form 10-K Summary	72

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, or otherwise.

PART I.

This Annual Report on Form 10-K includes forward-looking statements about our business and results of operations that are subject to risks and uncertainties. See “Note About Forward-Looking Statements” above. Factors that could cause or contribute to such risks and uncertainties include those discussed in Item 1A. “Risk Factors.” In addition to the risk factors discussed herein, we are also subject to additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of these risks and uncertainties develops into actual events, our business, financial condition or results of operations could be adversely affected.

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™, Curian™, ImmunoCard®, ImmunoCard STAT!®, LeadCare®, MyTaq™, PediaStat™, PREMIER®, revogene™ and SensiFAST™, 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 ® or ™ 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.

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 IVD manufacturers and researchers in immunological and molecular tests for human, animal, plant and environmental applications. The Company was incorporated in Ohio in 1976. Our principal corporate offices are located near Cincinnati, Ohio, USA.

Our website is 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. 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. Detailed information related to the reportable segments can be found in the following locations within this Annual Report on Form 10-K:

Type of Segment Information

Physical locations and activities

Revenue by geographic region

Financial information

Location within Annual Report on Form 10-K

Item 2. “Properties”

Item 7. “Management’s Discussion and Analysis of Financial Condition & Results of Operations” (hereafter “MD&A”)

Note 9 of Consolidated Financial Statements

Diagnostics Segment

Overview of Products and Markets

Our largest source of revenues is clinical diagnostic products, with our Diagnostics segment providing 68% of consolidated net revenues for fiscal 2019. As of September 30, 2019, our Diagnostics segment had approximately 485 employees in ten countries.

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 clinical diagnostic products span a broad menu of testing platforms and technologies, and also include transport media that store and preserve specimen samples from patient collection to laboratory testing. Our testing platforms include:

- **Real-time PCR Amplification (Revogene brand)** – high-sensitivity, fluorescent molecular platform suitable for automated sample prep and targeted nucleic acid amplification and detection from patient specimens. Assay platform can process 1-8 tests per run in about one hour. Current menu includes four FDA-cleared assays. Simple sample prep, footprint and test turnaround time make the Revogene platform suitable for Integrated Delivery Networks (“IDNs”) and hospital systems using a decentralized testing approach.
- **Isothermal DNA Amplification (Alethia brand)** – high sensitivity, molecular platform using LAMP (loop-mediated isothermal amplification) technology to process from 1 to 10 tests per run in generally under one hour; and requires no batching of samples. Following the June 2019 acquisition of the Revogene brand, efforts are underway to convert existing Alethia customers using *C. difficile*, Group A *Streptococcus* and Group B *Streptococcus* assays to the Revogene platform.
- **Lateral Flow Immunoassay (Curian brand)** – rapid fluorescence-based immunoassay platform highly compatible with detection of infectious agents in human clinical specimens; provides single step sample prep methodology with a rapid time-to-result analyzer readout in 20 minutes. The 510(k) application for the Curian instrument and its first assay, a stool antigen test for *H. pylori*, was submitted to FDA in September 2019, and commercial launch of the testing platform is expected in the first half of fiscal 2020.
- **Rapid Immunoassay (ImmunoCard and ImmunoCard STAT! brands)** – single-use immunoassays that have fast turnaround times (generally under 20 minutes); and can reduce expensive send-outs for hospitals and outpatient clinics.
- **Enzyme-linked Immunoassay (PREMIER brand)** – batch immunoassay platform that can process up to 96 tests per run; is highly accurate and economical; and is adaptable to automation.
- **Anodic Stripping Voltammetry (LeadCare and PediaStat brands)** – electrical chemical sensor platform for quantitative determination of lead levels in blood.

Our clinical diagnostic products are comprised of products used principally in the detection of infectious diseases caused by various bacteria, viruses, parasites and pathogens, along with the CLIA-waived LeadCare test for quantitative determination of blood lead levels. These products are grouped into the following product families:

Gastrointestinal Assays

Includes tests for the following, among others: *C. difficile*, Enterohemorrhagic *E. coli*, *Campylobacter jejuni* (Campy), *H. pylori*, Cryptosporidium, *giardia lamblia*, and calprotectin.

Respiratory Illness Assays

Includes tests for the following, among others: Group A *Streptococcus* (strep throat), Influenza, *M. pneumoniae* (Mycoplasma), *Bordetella pertussis* (whooping cough), and respiratory syncytial virus (RSV).

Blood Chemistry Assays

Tests for elevated lead levels in blood.

Other Assays

Includes tests for the following, among others: Group B *Streptococcus*, *Chlamydia trachomatis*, *Neisseria gonorrhoea*, Herpes Simplex Virus Type 1 & Type 2, and Malaria.

Our product portfolio includes over 140 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 current research and development pipeline for immunoassay products includes a new instrument that utilizes fluorescent chemistry, which improves workflow and test result readability. As noted above, this new platform is being branded under the “Curian” name. At the end of fiscal 2019, we submitted a 510(k) application to the FDA for an HpSA rapid immunoassay test for use with the Curian instrument, which we are expecting to introduce to the market during the second quarter of fiscal 2020. We expect to develop additional rapid immunoassay tests for use with the Curian instrument in 2020 and beyond.

Our current research and development pipeline for molecular assays to be run on our Revogene platform includes, among others, a gastrointestinal (“GI”) panel and a respiratory illness (“RI”) panel. We expect the 510(k) applications for the GI and RI panels to be submitted to the FDA in the latter part of fiscal 2020 and first half of fiscal 2021, respectively.

Market Trends

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. More importantly, within this market, there is a continuing shift from conventional testing, which requires highly trained personnel and lengthy turnaround times for test results, 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. With rapid and accurate diagnoses of infectious diseases, physicians can pinpoint appropriate therapies quickly, leading to faster recovery, shorter hospital stays and lower overall treatment cost. 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. Our *C. difficile*, Group B *Streptococcus*, Group A *Streptococcus* and *H. pylori* products are all examples of how a highly accurate diagnostic test on the front end can mitigate or reduce down-stream costs of antibiotic use, symptom-relieving drugs and hospital stays.

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's sales and distribution network consists of the following for each of the broad geographic regions we serve:

Americas

In the Americas, our sales and distribution network consists of a direct sales force complemented by independent distributors. The use of independent distributors allows our products to reach any size health care facility and also provides our customers the option to purchase our products directly from Meridian or through an authorized distributor. Two independent distributors accounted for 10% or more of consolidated revenues in fiscal 2019, 2018 and 2017: Cardinal Health 200 LLC ("Cardinal") and Fisher Scientific LLC ("Fisher"). Our Diagnostics segment revenues from Cardinal were approximately \$18,000, \$21,000 and \$22,000 during fiscal 2019, 2018 and 2017, respectively. Our Diagnostics segment revenues from Fisher were approximately \$17,000, \$22,000 and \$18,000 during fiscal 2019, 2018 and 2017, respectively.

EMEA

In Europe, the Middle East and Africa ("EMEA"), our sales and distribution network consists of direct sales personnel in Belgium, France and Italy, and independent distributors in other European countries, Africa and the Middle East. We maintain a distribution center near Milan, Italy.

ROW

We generally utilize independent distributors throughout the rest of the world ("ROW").

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. 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. 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 across our Curian, Revogene and PediaStat instrument platforms. 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 solely in-house, or substantially so. See "Operating Expenses" section within MD&A on page 28.

Manufacturing

Our immunoassay and molecular assay products require the production of highly specialized reagents, primers and enzymes. We produce the vast majority of our own immunoassay requirements. Reagents, primers and enzymes for our Revogene molecular assay products, as well as primers for our Alethia molecular assay products, 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. We believe that we have sufficient manufacturing and sourcing capacity for anticipated growth over the next several years, taking into consideration that we have the ability to add labor shifts and/or production lines as needed.

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 13%, 16% and 17% of consolidated revenues for fiscal 2019, 2018 and 2017, 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 a third party, 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 license agreement runs until 2036, 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 our *H. pylori* products, owned by us and which represented approximately 16%, 16% and 15% of consolidated revenues for fiscal 2019, 2018 and 2017, 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 *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. In October 2018, we entered into a strategic collaboration with DiaSorin to sell *H. pylori* tests, one of only three other companies that market FDA-cleared tests to detect *H. pylori* antigen in stool samples in the U.S. market. 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. In the first half of fiscal 2020, we expect to launch Curian HpSA, our first assay on the new Curian platform, for which the 510(k) application was submitted to the FDA in September 2019. We expect that this product will help us protect existing rapid assay accounts using the advantages of the Curian analyzer. However, 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 in Cincinnati and Billerica are subject to periodic inspection by the FDA. See page 25 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, 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.

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.

Seasonal Factors and Sporadic Outbreaks

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. While we believe that the breadth of our diagnostic product lines reduces the risk that infections subject to seasonality and sporadic outbreaks will cause significant variability in diagnostic revenues, we can make no assurance that revenues will not be impacted period over period by such factors.

Life Science Segment

Overview of Products and Markets

Our Life Science segment focuses on the development, manufacture, sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, and bioresearch reagents used by researchers, agri-bio companies and IVD manufacturing companies. As of September 30, 2019, our Life Science segment had approximately 175 employees in six countries.

Most of the revenues for our Life Science segment currently come from the manufacture, sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, and bioresearch reagents used by IVD manufacturing companies focused on the development of immunoassay and molecular assay tests. Approximately 80% of Life Science revenues are generated from the industrial market, defined as IVD manufacturers. This continues to be an increasing focus for our molecular reagent products, which historically have been marketed to the academic/research customers that comprise the remaining 20% of Life Science revenues. We utilize direct sales teams in key countries such as the U.S., the U.K., France, Germany, and Australia. In order to further pursue revenue opportunities in Asia, and China in particular, during fiscal 2017 we established a wholly foreign owned enterprise (“WFOE”) location in Beijing, China, after having operated a representative office there since fiscal 2015. The WFOE employs a business development staff and imports product for sale to customers in China. We utilize a network of distributors in other major countries. During fiscal 2019, 24% of third-party revenues for this segment were from two IVD manufacturing customers.

Our Life Science products are marketed to IVD manufacturing customers as a source of raw materials for their immunoassay products, or as an outsourced step in their manufacturing processes. For example, we supply a number of major IVD manufacturers with proteins used to detect hepatitis A virus and rubella virus. Sales efforts are focused on multi-year supply arrangements in order to provide stability in volumes and pricing. We believe this benefits both us and our customers.

We utilize independent distributors to market molecular biology products to academic/research customers. These products are used in measuring DNA and RNA in human, animal, plant and environmental applications. These reagents improve the purity, yield and speed of PCR reactions. Products such as MyTaq and SensiFAST are examples of this type of PCR/qPCR reagent.

Market Trends

As certain global markets become increasingly accessible to us, most notably the Asia-Pacific region, geographic expansion continues to be a significant strategy for our Life Science segment, along with further penetration into industrial markets with our molecular biology products.

Competition

The market for bulk biomedical reagents is highly competitive. Important competitive factors include product quality, price, customer service and reputation. We face competitors, many of which have greater financial,

research and development, sales and marketing, and manufacturing resources, and where sole-source supply arrangements do not exist. Customers also may choose to manufacture their biomedical reagents in-house rather than purchase from outside vendors such as Meridian.

The academic/research market is highly fragmented. Individual purchases are typically of small quantities. The breadth of product offerings, quality, price and service, including on-line capabilities and technical resources, are important factors to building customer loyalty and repeat purchases.

Research and Development

The focus of research and development activities for the Life Science segment is targeted around improving reagents, particularly molecular reagents. 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 28.

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.

Acquisitions

Acquisitions have played an important role in the growth of our businesses. Our acquisition objectives include, among other things: (i) enhancing product offerings; (ii) improving product distribution capabilities; (iii) providing access to new markets; and/or (iv) providing access to key biologicals or new technologies that lead to new products. Although we cannot provide assurance that we will consummate additional acquisitions in the future, nor can we provide assurance that any acquisitions will accomplish these objectives, we expect that the potential for acquisitions will continue to provide opportunities for revenue and earnings growth in the future.

During June 2019, we acquired the business of GenePOC Inc. (“GenePOC”). A description of the GenePOC acquisition appears in Note 2 of the accompanying Consolidated Financial Statements.

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 approximated \$76,000 or 38% of consolidated fiscal 2019 revenues, \$73,000 or 34% of consolidated fiscal 2018 revenues, and \$67,000 or 33% of consolidated fiscal 2017 revenues. 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 2018 had an approximate \$2,200 unfavorable impact on fiscal 2019 revenues; \$1,150 within the Diagnostics segment and \$1,050 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 2018; \$1,400 within the Diagnostics segment and \$800 within the Life Science segment. Due to natural hedge relationships with expenses, both cost of sales and operating expenses, the overall impact of exchange rate fluctuations on operating income was not significant during fiscal 2019, 2018 and 2017.

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.

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

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 product 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 26% and 29% of the Diagnostics segment's total revenues for fiscal 2019 and fiscal 2018, respectively, or approximately 18% and 20%, 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. While we believe that the breadth of our diagnostic product lines reduces the risk that infections subject to seasonality and sporadic outbreaks will cause significant variability in diagnostic revenues, 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.

The Patient Protection and Affordable Care Act includes a medical device excise tax for which a moratorium has been in place. However, this moratorium is scheduled to expire December 31, 2019. Our Diagnostics segment’s products are generally subject to this tax. We are unable to predict if Congress will extend the current moratorium or altogether repeal the tax. Without Congressional legislative action, the medical device excise tax will return effective January 1, 2020.

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 two diagnostic manufacturing customers were 24% and 18% of the Life Science segment’s total revenues for fiscal 2019 and fiscal 2018, respectively; and 8% and 5% of our consolidated revenues for fiscal 2019 and fiscal 2018, respectively. Our Life Science segment has five other significant customers, which together comprised 11% of the segment’s total revenues for each of fiscal 2019 and fiscal 2018. Any significant alteration of buying patterns from these customers could adversely affect our period over period revenues and results of operations.

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

The patents for our *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 *H. pylori* products, high margin products which represent approximately 16% 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. 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. In the first half of fiscal 2020, we expect to launch Curian HpSA, our first assay on the new Curian platform for which the 510(k) was submitted to the FDA in September 2019. We expect that this product will help us protect existing rapid assay accounts using the advantages of the Curian analyzer. However, 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 2019, approximately 20% 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 and Euro. 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. In November 2019, we submitted to the FDA our written responses to the five Form 483 observations and have implemented a remediation plan that we are actively working. 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 25.

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 upon its commercialization during the first half of fiscal 2020, an additional third party will manufacture 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 11% of consolidated revenues in each of fiscal 2019, 2018 and 2017. 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.

See Item 3. “Legal Proceedings” for a discussion of the status of certain litigation related to our intellectual property.

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.

Other Risks Affecting Our Business

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, 2019, we had \$75,824 outstanding on a \$125,000 bank revolving credit facility.

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 negotiating the terms of its exit from the European Union ("Brexit"). In November 2018, the U.K. and the European Union agreed upon a draft Withdrawal Agreement that sets out the terms of the U.K.'s departure, including commitments on citizen rights after Brexit, a financial settlement from the U.K., and a transition period to allow time for a future trade deal to be agreed. The U.K. Parliament has not approved the Withdrawal Agreement. As such, the date and the terms of the U.K.'s withdrawal from the European Union remain highly uncertain.

Any impact of Brexit depends on the terms of the U.K.'s withdrawal from the European Union, if it ultimately occurs. The ongoing uncertainty on the status of the final Withdrawal Agreement could lead to economic stagnation until an ultimate resolution with respect to Brexit occurs. If the U.K. leaves the European Union with no agreement, 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 a future trade deal, the U.K.'s trade with the European Union and the rest of the world would 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 an agreement setting forth the terms of the U.K.'s withdrawal from the European Union is 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. 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.

Risks Related to Our Common Stock

Material weaknesses in our internal control over financial reporting could be identified, which if not properly corrected, could materially adversely affect our operations and result in material misstatements in our financial statements.

During fiscal 2017, the Company identified a material weakness in internal control over financial reporting, which has been remediated. However, the Company can make no assurances that a material weakness will not be identified in the future or that, if identified, it will be properly corrected. In the event we are unable to remediate a material weakness identified in the future, we may be unable to provide holders of our securities with required financial information in a timely and reliable manner, and we may incorrectly report financial information. Either of these events could have a material adverse effect on our operations, investor, supplier and customer confidence in our reported financial information, and/or the trading price of our common stock.

The authority of our board to issue preferred stock 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.

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.

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, and our PCR-based molecular manufacturing and research and development operations are located in an approximately 24,000 square foot leased facility in Quebec City, Canada. 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.

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 10,500 square feet of sales, warehouse and manufacturing space; Sydney – approximately 5,000 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 November 15, 2017, Barbara Forman filed a class action complaint in the United States District Court for the Southern District of Ohio (the Court) naming Meridian, its former Chief Executive Officer and former Chief Financial Officer (in their capacities as such) as defendants. An amended complaint was filed on April 16, 2018 and the Company believes the essential elements of the amended complaint are the same. On July 9, 2019, a settlement was reached with the plaintiff that provides for a \$2.1 million payment by the Company. On October 9, 2019, the Court granted a motion for preliminary approval of the settlement, and on November 7, 2019, the settlement amount was paid from the Company's Directors and Officers insurance policy into a plaintiff escrow account. The Court has scheduled a final approval hearing for March 2020. Because the settlement was a covered claim under our Directors and Officers insurance policy, no provision for litigation losses has been included within the accompanying Consolidated Statements of Operations for fiscal 2019, 2018 or 2017.

On December 6, 2017, Michael Edelson filed a derivative complaint in the United States District Court for the Southern District of Ohio naming Meridian, its former Chief Executive Officer, former Chief Financial Officer and certain members of Meridian's Board of Directors and Audit Committee (in their capacities as such) as defendants. The complaint alleges that Meridian made false and misleading representations concerning certain of Magellan's lead test systems at or around the time of Meridian's acquisition of Magellan and subsequent thereto, and the complaint alleges that certain members of the Board of Directors and Audit Committee breached their fiduciary duties in their oversight of the Company's public disclosures and corporate governance matters. The complaint sought compensatory damages, equitable relief relating to corporate governance matters and attorneys' fees. On October 9, 2019, Court granted plaintiff's motion for voluntary dismissal. Accordingly, no provision for litigation losses has been included within the accompanying Consolidated Statements of Operations for fiscal 2019, 2018 or 2017.

Approximately \$30 and \$600 of expense for attorneys' fees related to the above two class action matters is included within the accompanying Consolidated Statements of Operations for fiscal 2019 and 2018, respectively. Amounts expensed in fiscal 2018 included a \$500 deductible under our Directors and Officers insurance policy.

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 \$1,585 and \$775 of expense for attorneys' fees related to this matter is included within the accompanying Consolidated Statements of Operations for fiscal 2019 and 2018, respectively.

On October 9, 2018, the Company and DiaSorin Inc. entered into a strategic collaboration to sell DiaSorin's *Helicobacter pylori* stool antigen test to detect *H. pylori* for use on its automated LIAISON platform under the Meridian brand name worldwide. The new collaboration resulted in the termination of all pending legal disputes between the two parties and will expand the previous agreement between DiaSorin and Meridian, which focused on the sale, by DiaSorin, of co-developed products in major countries in continental Europe. Approximately \$50, \$2,965 and \$630 of expense for attorneys' fees related to this matter is included within the accompanying Consolidated Statements of Operations for fiscal 2019, 2018 and 2017, respectively.

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 20 of this Annual Report.

Market Information

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

Holdings of our Common Stock

As of September 30, 2019, there were approximately 600 holders of record and approximately 10,550 beneficial owners of our common shares.

Dividends

"Quarterly Financial Data (Unaudited)" relating to our dividends in Note 11 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, 2018 and 2017. 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 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. The declaration and amount of

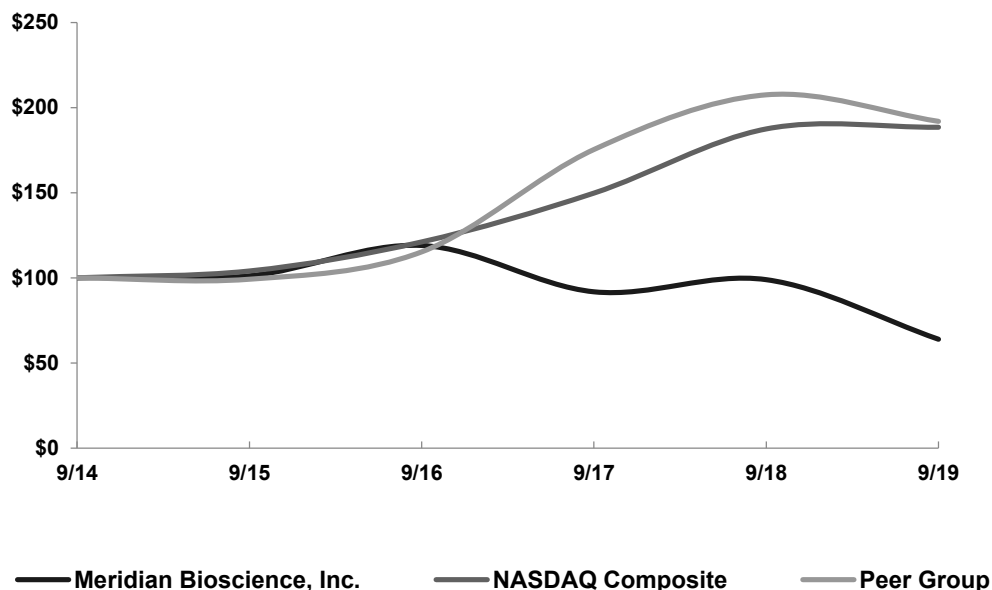
dividends will be determined by the board of directors in its discretion based upon its evaluation of earnings, cash flow requirements and future business developments and opportunities, including acquisitions. We paid dividends of \$0.25, \$0.50 and \$0.575 per share in fiscal 2019, 2018 and 2017, respectively.

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 each index, and in the peer group (including reinvestment of dividends) was \$100 on September 30, 2014 and tracks it through September 30, 2019.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

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



*\$100 invested on 9/30/14 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,	2019	2018	2017	2016	2015	
Net revenues	\$ 201,014	\$ 213,571	\$ 200,771	\$ 196,082	\$ 194,830	
Gross profit	118,325	130,697	124,292	127,212	121,882	
Operating income	32,699	31,584	37,382	51,378	56,060	
Net earnings	24,382	23,849	21,557	32,229	35,540	
Basic earnings per share	\$ 0.57	\$ 0.56	\$ 0.51	\$ 0.77	\$ 0.85	
Diluted earnings per share	\$ 0.57	\$ 0.56	\$ 0.51	\$ 0.76	\$ 0.85	
Cash dividends declared per share	\$ 0.250	\$ 0.500	\$ 0.575	\$ 0.800	\$ 0.800	
Book value per share	\$ 4.47	\$ 4.14	\$ 4.02	\$ 3.95	\$ 3.96	

Balance Sheet Information						
As of September 30,	2019	2018	2017	2016	2015	
Current assets	\$ 144,761	\$ 139,053	\$ 133,875	\$ 126,791	\$ 119,422	
Current liabilities	20,914	24,173	22,887	22,571	15,251	
Total assets	325,478	251,377	249,777	252,028	183,282	
Long-term debt obligations	75,824	50,180	54,647	58,360	-	
Shareholders' equity	190,967	175,418	169,585	166,472	165,873	

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 20 of this Annual Report.

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

Results of Operations:

Fourth Quarter

Net earnings for the fourth quarter of fiscal 2019 decreased 24% to \$4,103, or \$0.10 per diluted share, from net earnings for the fourth quarter of fiscal 2018 of \$5,434, or \$0.13 per diluted share. The fiscal 2019 fourth quarter results include \$1,714 of costs associated with acquisition activities, restructuring activities and selected legal proceedings (combined impact on net earnings of \$1,296, or \$0.03 per diluted share). The fiscal 2018 fourth quarter results include \$4,576 of costs associated with restructuring activities and selected legal proceedings, along with certain one-time tax effects of the U.S. tax reform act enacted in December 2017 (combined impact on net earnings of \$3,145, or \$0.07 per diluted share). Consolidated revenues for the fourth quarter of fiscal 2019 totaled \$50,846, a decrease of 4% compared to the fourth quarter of fiscal 2018, also decreasing 3% on a constant-currency basis.

Revenues for the Diagnostics segment for the fourth quarter of fiscal 2019 decreased 9% compared to the fourth quarter of fiscal 2018 (also 9% on a constant-currency basis), comprised of a 22% decrease in molecular assay products and a 6% decrease in immunoassay and blood chemistry assay products. With a 13% decrease in its molecular reagents products and a 21% increase in its immunological reagents products, revenues for our Life Science segment increased 7% in the fourth quarter of fiscal 2019 compared to the fourth quarter of fiscal 2018. On a constant-currency basis, revenues for our Life Science Segment increased 9%.

The fourth quarter Diagnostics revenues reflect continued competitive pressures in a number of our products, particularly *C. difficile* and foodborne, volume and pricing declines in certain gastrointestinal products, and the effects of initially lighter shipments of respiratory products in advance of the upcoming season. Life Science revenues for the fourth quarter reflect double-digit growth from IVD customers purchasing immunological reagents in the EMEA region, as well as China, offset by declines in transitioning our academic business to independent distributors in the Americas region.

Fiscal Year

Net earnings for fiscal 2019 increased 2% to \$24,382, or \$0.57 per diluted share, from net earnings for fiscal 2018 of \$23,849, or \$0.56 per diluted share. Fiscal 2019 results include \$6,230 of costs associated with acquisition activities, restructuring activities and selected legal proceedings (combined impact on net earnings of \$4,760, or \$0.11 per diluted share). Fiscal 2018 results include \$13,051 of costs associated with restructuring activities and selected legal proceedings, along with certain one-time tax effects of the U.S. tax reform act enacted in December 2017 (combined impact on net earnings of \$7,856, or \$0.18 per diluted share). Consolidated revenues decreased 6% to \$201,014 for fiscal 2019 compared to fiscal 2018, decreasing 5% on a constant-currency basis.

In fiscal 2019, revenues for the Diagnostics segment decreased 9% compared to fiscal 2018 (8% on a constant-currency basis). This decrease is comprised of a 22% decrease in our molecular assay products and a 5% decrease in immunoassay and blood chemistry assay products. With a 5% decrease in its molecular reagents business and a 6% increase in its immunological reagents business, revenues of our Life Science segment increased 2% during fiscal 2019 compared to fiscal 2018, increasing 3% on a constant-currency basis.

Update on Lead Testing

On June 29, 2017, the FDA, in connection with its Safety Notification related to Magellan's LeadCare testing systems for venous blood samples, issued to Magellan its Form 483, Inspectional Observations. The FDA issued a related Warning Letter on October 23, 2017. As a result of these activities, during our 2017 third fiscal quarter, it was determined that a potential impairment of goodwill recorded in connection with the acquisition of Magellan had occurred (i.e., a "triggering event"). An impairment charge of \$6,628, on both a pre-tax and after-tax basis, was recorded during the fiscal 2017 third quarter as set forth in Note 1(h), "*Summary of Significant Accounting Policies – Intangible Assets*" of the accompanying Consolidated Financial Statements. As also previously disclosed and 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 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 483 observations. In November 2019, we submitted to the FDA our written responses to the five Form 483 observations and have implemented a remediation plan that we are actively working. 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.

During fiscal 2019, 2018 and 2017, we incurred approximately \$1,800 in aggregate remediation costs, primarily related to regulatory consultants and studies required to reinstate our venous blood sample claim. 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 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, or 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 diagnostic products in Cincinnati, Ohio and Quebec City, Canada, and manufacturing operations for products detecting elevated lead levels in blood 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 the severity of seasonal diseases and outbreaks, 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 customers and foreign currency exchange rates.

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 acquisition of the Revogene molecular diagnostics platform, 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* and Group B *Streptococcus* assays. During our first 120 days since acquiring the Revogene platform, we have approximately 60 instrument installations. For the Curian immunoassay diagnostics platform, we submitted a 510(k) for the instrument and first assay, a test for *H. pylori* antigen in stool, in September 2019. We believe the advantages of the Curian analyzer will help protect our existing rapid test accounts.

Gastrointestinal Assays

During fiscal 2019, revenues from our gastrointestinal products, which include tests for *C. difficile*, *H. pylori* and certain foodborne pathogens, among others, totaled \$68,977. This represents a 13% decrease from fiscal 2018 and follows a less than 1% increase during fiscal 2018. We continue to face pricing and volume pressures within this product category that will carry into fiscal 2020 and beyond for our current products. 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. 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 *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 *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. In October 2018, we entered into a strategic collaboration with DiaSorin to sell *H. pylori* tests, one of only three other companies that market FDA-cleared tests to detect *H. pylori* antigen in stool samples in the U.S. market. 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

Including tests for influenza, RSV, Group A Strep, Pertussis, and Mycoplasma pneumonia, among others, our respiratory illness product revenues decreased 8% in fiscal 2019, following a 21% increase in fiscal 2018. These revenue levels reflect a lighter 2018 – 2019 respiratory season, as compared to the particularly strong 2017 – 2018 respiratory season, as measured by the rate of laboratory-confirmed influenza hospitalizations (published by the CDC).

Blood Chemistry Assays

Revenues from our sale of products to test for elevated levels of lead in blood remained relatively flat during fiscal 2019 at \$19,082. This follows fiscal 2018 revenues from such products increasing 5% over fiscal 2017. Nominal favorable pricing offset nominal volume declines in fiscal 2019.

Life Science Products

During fiscal 2019, revenues from our Life Science segment increased 2%, with revenues from molecular reagent sales decreasing 5% compared to fiscal 2018 and revenues from immunological reagent sales increasing 6%. Life Science segment revenues increased 10% in fiscal 2018, with revenues from molecular reagent sales increasing 12% compared to fiscal 2017 and revenues from immunological reagent sales increasing 9%. Our Life Science segment's growth was impacted by the movement in currency exchange rates since fiscal 2018, with revenues increasing 3% on a constant-currency basis over fiscal 2018. During fiscal 2019, our Life Science segment continued to benefit from sales into China, with such sales totaling approximately \$8,400 during fiscal 2019 – representing an approximate 1% increase over fiscal 2018.

Foreign Currency

Fluctuations in foreign currency exchange rates since fiscal 2018 had an approximate \$2,200 unfavorable impact on fiscal 2019 revenues; \$1,150 within the Diagnostics segment and \$1,050 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 2018; \$1,400 within the Diagnostics segment and \$800 within the Life Science segment. Due to natural hedge relationships with expenses, both cost of sales and operating expenses, the overall impact of exchange rate fluctuations on net earnings was not significant during fiscal 2019, 2018 or 2017.

Significant Customers

Revenue concentrations related to certain customers within our Diagnostics and Life Science segments are set forth in Note 9 of the accompanying Consolidated Financial Statements.

Gross Profit:

	2019	2018	2017	2019 vs. 2018 Inc (Dec)	2018 vs. 2017 Inc (Dec)
Gross Profit	\$ 118,325	\$ 130,697	\$ 124,292	(9 %)	5 %
Gross Profit Margin	59%	61%	62%	-2 points	-1 point

The overall gross profit margin decrease during fiscal 2019 primarily results from 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 newly acquired Quebec facility where Revogene instruments and test devices are made; and (iv) operating segment mix. The overall decrease in the gross profit margin from fiscal 2017 to fiscal 2018 reflects the combined effects of: (i) pricing pressure in our Diagnostics segment; (ii) mix of products sold, particularly decreased contribution from certain of our higher margin gastrointestinal assays; and (iii) operating segment mix.

**Operating Expenses -
Segment Detail**

	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
Fiscal 2017:					
Diagnostics	\$ 13,433	\$ 22,942	\$ 13,268	\$ 6,628	\$ 56,271
Life Science	2,603	9,446	7,493	-	19,542
Corporate	-	-	10,335	762	11,097
Total 2017 Expenses	\$ 16,036	\$ 32,388	\$ 31,096	\$ 7,390	\$ 86,910
Fiscal 2018:					
Diagnostics	\$ 13,742	\$ 25,002	\$ 19,397	\$ 4,032	\$ 62,173
Life Science	3,047	9,466	8,111	1,240	21,864
Corporate	-	-	7,297	7,779	15,076
Total 2018 Expenses	\$ 16,789	\$ 34,468	\$ 34,805	\$ 13,051	\$ 99,113
Fiscal 2019:					
Diagnostics	\$ 14,711	\$ 23,058	\$ 19,191	\$ 3,446	\$ 60,406
Life Science	3,237	5,388	6,034	188	14,847
Corporate	-	-	7,777	2,596	10,373
Total 2019 Expenses	\$ 17,948	\$ 28,446	\$ 33,002	\$ 6,230	\$ 85,626

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

	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
2017 Expenses	\$ 16,036	\$ 32,388	\$ 31,096	\$ 7,390	\$ 86,910
% of Revenues	8%	16%	15%	4%	43%
Fiscal 2018 Increases (Decreases):					
Diagnostics	309	2,060	6,129	(2,596)	5,902
Life Science	444	20	618	1,240	2,322
Corporate	-	-	(3,038)	7,017	3,979
2018 Expenses	\$ 16,789	\$ 34,468	\$ 34,805	\$ 13,051	\$ 99,113
% of Revenues	8%	16%	16%	6%	46%
% Increase	5%	6%	12%	77%	14%
Fiscal 2019 Increases (Decreases):					
Diagnostics	969	(1,944)	(206)	(586)	(1,767)
Life Science	190	(4,078)	(2,077)	(1,052)	(7,017)
Corporate	-	-	480	(5,183)	(4,703)
2019 Expenses	\$ 17,948	\$ 28,446	\$ 33,002	\$ 6,230	\$ 85,626
% of Revenues	9%	14%	16%	3%	43%
% Increase (Decrease)	7%	(17%)	(5%)	(52%)	(14%)

Total operating expenses fluctuated during fiscal 2019 and fiscal 2018 primarily as a result of the combined effects of the following:

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 being more than 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).

Fiscal 2018 increase

- Increased Selling & Marketing costs, reflecting increased commission and bonus payments made in connection with the increased revenue levels, along with costs associated with the new branding strategy;
- Increased General & Administrative costs due in large part to the cash incentive compensation resulting from the revenue and net earnings results achieved, along with increased Quality System remediation costs related to Magellan;

- Increased restructuring costs, reflecting: (i) compensation and benefits for our previous Executive Chairman and CEO throughout fiscal 2018, the period during which we also have the compensation and benefits of a new CEO; and (ii) the costs of terminations and related expenses incurred in connection with realigning our business structure; and
- Increased legal costs related to the matters discussed in Item 3. “Legal Proceedings”.

Operating Income

Operating income increased 4% in fiscal 2019, following a 15% decrease in fiscal 2018, as a result of the factors discussed above, including the acquisition-related, restructuring and selected legal costs in each of the fiscal years and the Magellan goodwill impairment charge in fiscal 2017.

Other Income and Expense

Other income and expense in fiscal 2019, 2018 and 2017 includes interest costs on the Company’s long-term borrowings, which are comprised of the following during these fiscal years:

- Draws on the revolving credit facility used to fund acquisition of the business of GenePOC and pay off the term loan used to fund the March 2016 acquisition of Magellan (May 2019 – September 2019), bearing interest at a fluctuating rate tied to, at the Company’s option, either the federal funds rate or LIBOR.
- Term loan used to fund the acquisition of Magellan (March 2016 – May 2017), bearing interest at an effective rate of 2.76%.

Income Taxes

The effective rate for income taxes was 23%, 21% and 41% for fiscal 2019, 2018 and 2017, respectively. These rates reflect the combined effect of various components of the tax reform act (see Note 6, “*Income Taxes*” of the accompanying Consolidated Financial Statements) including: (i) the lowering of the applicable tax rate; (ii) the accompanying re-measurement of deferred tax balances at the lower rate; and (iii) the various foreign-income related items, such as the repatriation transition tax, the tax deduction related to Foreign Derived Intangible Income, and the tax related to Global Intangible Low-Taxed Income and foreign tax credits.

Impact of Inflation

To the extent feasible, we have consistently followed the practice of adjusting our prices to reflect the impact 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 2019, 2018 or 2017.

Liquidity and Capital Resources:

Liquidity

Our cash flow and financing requirements are determined by analyses of operating and capital spending budgets, debt service, and consideration of common share dividends. 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.

Considering the various worldwide geo-political and geo-economic conditions (including Brexit, as more fully discussed within the “Risk Factors” section of Part 1A), we do not expect macroeconomic conditions to have a significant impact on our liquidity needs, financial condition or results of operations, although no assurances can be made in this regard. 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 \$125,000 bank revolving credit facility, which totaled approximately \$49,200 as of September 30, 2019. 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.

As of September 30, 2019, our cash and equivalents balance is \$62,397 or \$2,634 higher than at the end of fiscal 2018. This increase results in large part from the cash flows from operating activities being more than sufficient to cover capital expenditures, shareholder dividends for two quarters and debt service. 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 12 months.

Following the declaration of a \$0.125 first quarter cash dividend consistent with the previously established \$0.50 per share annual indicated dividend rate, effective for the second quarter of fiscal 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 5, “*Bank Credit Arrangements*” of the accompanying Consolidated Financial Statements, on May 24, 2019, in connection with the acquisition of the GenePOC business, the Company executed a new five-year \$125,000 revolving credit facility to replace our previously-existing \$30,000 credit facility. The new credit facility is secured by substantially all of our assets and includes certain restrictive financial covenants. To date, we have drawn down \$75,824 on this new facility, using the proceeds to repay our previously-existing term loan and, along with cash on-hand, fund the acquisition of the GenePOC business.

Our capital expenditures totaled \$3,797 for fiscal 2019 and were largely related to laboratory and manufacturing equipment. During fiscal 2020 our capital expenditures are estimated to range between approximately \$4,000 to \$5,000, with the actual amount dependent upon actual operating results and the phasing of certain projects. Such expenditures may be funded with cash and equivalents on hand, operating cash flows and/or availability under the \$125,000 revolving credit facility discussed above.

Known Contractual Obligations:

In addition to the obligations related to the revolving credit facility noted above and detailed in Note 5, “*Bank Credit Arrangements*” of the accompanying Consolidated Financial Statements, the Company’s known contractual obligations and their related due dates were as follows as of September 30, 2019:

	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating leases ⁽¹⁾	\$ 6,567	\$ 1,528	\$ 3,711	\$ 1,145	\$ 183
Purchase obligations ⁽²⁾	14,995	14,203	737	55	-
Acquisition price holdback and contingent consideration ⁽³⁾	75,000	-	75,000	-	-
Uncertain income tax positions liability and interest ⁽⁴⁾	511	511	-	-	-
Total	\$ 97,073	\$ 16,242	\$ 79,448	\$ 1,200	\$ 183

- (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, Meridian's maximum remaining consideration to be paid totals \$75,000. As noted below and detailed in Note 2, "*Acquisition of Business of GenePOC*" of the accompanying Consolidated Financial Statements, this amount is comprised of: (i) a \$5,000 purchase price holdback; and (ii) up to \$70,000 of payments contingent upon the achievement of certain product development milestones and financial performance targets, the preliminary valuation of which totals approximately \$27,200 as of September 30, 2019.
- (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 84% 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 \$2,100 in fiscal 2020.

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, "*Acquisition of Business of GenePOC*" 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 and Euro. 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 26% of the segment's total revenues or 18% of consolidated revenues for fiscal 2019. Additionally, our three major product families – gastrointestinal, respiratory illnesses and blood chemistry – accounted for 84% of our Diagnostics segment's third-party revenues during fiscal 2019, and 57% of our fiscal 2019 consolidated revenues.

Our Life Science segment's revenues from sales of purified antigens and reagents to two diagnostics manufacturing customers were 24% of the segment's total revenues for fiscal 2019, and 8% of our fiscal 2019 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 polices requires the use of significant estimates and assumptions, and the carrying values of related assets and liabilities are material.

<u>Accounting Policy</u>	Location Within Consolidated Financial Statements	<u>Examples of Key Estimate Assumptions</u>
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 contingent consideration
Income Taxes	Note 1(l) and Note 6	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 24.

ITEM 8.

FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

Management’s Report on Internal Control over Financial Reporting	35
Reports of Independent Registered Public Accounting Firm	36
Consolidated Statements of Operations for the years ended September 30, 2019, 2018 and 2017	41
Consolidated Statements of Comprehensive Income for the years ended September 30, 2019, 2018 and 2017	42
Consolidated Statements of Cash Flows for the years ended September 30, 2019, 2018 and 2017	43
Consolidated Balance Sheets as of September 30, 2019 and 2018	44
Consolidated Statements of Shareholders’ Equity for the years ended September 30, 2019, 2018 and 2017	46
Notes to Consolidated Financial Statements	47
Schedule No. II – Valuation and Qualifying Accounts for the years ended September 30, 2019, 2018 and 2017	74

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, 2019, 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, 2019. The Company's assessment of and conclusion on the effectiveness of its internal control over financial reporting did not include the internal controls of Meridian Bioscience Canada, Inc. ("GenePOC"), which was acquired during fiscal 2019 and the results of which since the date of acquisition were included in the 2019 consolidated financial statements. GenePOC constituted \$9,250 or 2.84% of the Company's total assets as of September 30, 2019, and \$75 or 0.04% of total net revenues, for the year ended September 30, 2019.

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 26, 2019

/s/ Bryan T. Baldasare
Bryan T. Baldasare
Executive Vice President and
Chief Financial Officer
November 26, 2019

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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2019, 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, 2019, 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 26, 2019 expressed an unqualified opinion.

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 supporting 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 matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Distributor price adjustment accrual (rebate reserve)

As described further in Note 1(i) to the consolidated financial statements, revenue is reduced at the date of sale for product price adjustments for 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. The balance of the accrual was \$3.4 million at September 30, 2019. We identified the distributor price adjustment accrual (referred to as the rebate reserve) as a critical audit matter.

The principal consideration for our determination that the rebate reserve is a critical audit matter is the high degree of auditor subjectivity necessary in evaluating certain inputs and assumptions made by management in estimating the amount of the rebate reserve. The nature of audit evidence includes unobservable inputs and assumptions used by management in the estimate, and reliance on a customized sales report by product line. The reserve has a high degree of estimation uncertainty given management's judgments used to determine the reserve, specifically the use of key assumptions such as average selling price, purchasing trends of distributors and historical product sales and product volume data used to predict future sales and volume levels.

Our audit procedures related to the rebate reserve included the following, among others.

- We tested the design and operating effectiveness of controls relating to management's calculation and review of the reserve which included verifying the completeness of the input data, mathematical accuracy of the calculation and evaluating the reasonableness of key assumptions used in the calculation.
- We tested the reserve calculation prepared by management by performing specific procedures on the key inputs and assumptions such as the monthly sales volume, validity of distributor agreements and applied reserve percentage. The procedures performed are as follows:
 - We tested the completeness and accuracy of the historical sales (including average selling price) and volume report used in the calculation of the reserve by agreeing total sales to accounting records and tracing a sample of individual sales to supporting audit evidence, such as purchase orders, shipping documents and invoices.
 - We evaluated the existence and validity of distributor agreements by obtaining a sample of issued credit memos and executed distributor agreements to test compliance with the stated terms in the corresponding agreements.
 - We analyzed year over year trends in the reserve in comparison with revenue trends to further evaluate reasonableness of the estimate and consistency with expectations.

Valuation of intangible assets and contingent consideration

As described in Note 2 to the consolidated financial statements, the Company completed an acquisition which resulted in goodwill of \$35.1 million, intangible assets of \$40.4 million, and contingent consideration of \$27.2 million. The determination of the fair value of the intangible assets acquired and contingent consideration required management, with the help of a third-party valuation specialist, to make significant estimates and assumptions including the assumed sales growth rate, margin percentages, economic life and discount rate. We identified the valuation of intangible assets and contingent consideration as a critical audit matter.

The principal consideration for our determination that the valuation of intangible assets and contingent consideration associated with the acquisition is a critical audit matter is the subjective auditor judgment required in evaluating the inputs and assumptions used by management in determining fair value. The valuation of the intangible assets and contingent consideration are subject to higher estimation uncertainty due to management judgments in determining key assumptions that include the assumed sales growth rate, margin percentages, economic life and discount rate. Changes in these significant assumptions could have a significant impact on the fair value of the intangible assets and contingent consideration.

Our audit procedures related to the valuation of intangible assets and contingent consideration 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 valuation report for the completeness and mathematical accuracy of the data, and evaluating the reasonableness of assumptions used in the calculation such as economic life and discount rate.
- We utilized a valuation specialist to assist in evaluating the appropriateness of the Company's valuation models developed for acquired assets and evaluating the reasonableness of significant assumptions used including the assumed sales growth rate, margin percentages, economic life and discount rate as compared to industry/market data.

- We evaluated whether the assumptions used were reasonable by considering past performance of similar technological 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 26, 2019

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, 2019, 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, 2019, 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, 2019, and our report dated November 26, 2019 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 Canada, Inc. (“GenePOC”), a wholly-owned subsidiary, whose financial statements reflect total assets and revenues constituting 2.84 and 0.04 percent, respectively, of the related consolidated financial statement amounts as of and for the year ended September 30, 2019. As indicated in Management’s Report, GenePOC was acquired during fiscal 2019. Management’s assertion on the effectiveness of the Company’s internal control over financial reporting excluded internal control over financial reporting of GenePOC.

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 26, 2019

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

For the Year Ended September 30,	2019	2018	2017
Net Revenues	\$ 201,014	\$ 213,571	\$ 200,771
Cost of Sales	82,689	82,874	76,479
Gross Profit	118,325	130,697	124,292
Operating Expenses:			
Research and development	17,948	16,789	16,036
Selling and marketing	28,446	34,468	32,388
General and administrative	33,002	34,805	31,096
Acquisition-related costs	1,808	-	-
Restructuring costs	2,839	8,706	134
Selected legal costs	1,583	4,345	628
Goodwill impairment charge	-	-	6,628
Total operating expenses	85,626	99,113	86,910
Operating Income	32,699	31,584	37,382
Other Income (Expense):			
Interest income	681	418	171
Interest expense	(1,945)	(1,520)	(1,642)
Other, net	122	(102)	518
Total other expense	(1,142)	(1,204)	(953)
Earnings Before Income Taxes	31,557	30,380	36,429
Income Tax Provision	7,175	6,531	14,872
Net Earnings	\$ 24,382	\$ 23,849	\$ 21,557
Earnings Per Share Data:			
Basic earnings per common share	\$ 0.57	\$ 0.56	\$ 0.51
Diluted earnings per common share	\$ 0.57	\$ 0.56	\$ 0.51
Common shares used for basic earnings per common share	42,571	42,325	42,188
Effect of dilutive stock options and restricted share units	328	429	383
Common shares used for diluted earnings per common share	42,899	42,754	42,571
Dividends declared per common share	\$ 0.250	\$ 0.500	\$ 0.575
Anti-dilutive Securities:			
Common share options and restricted share units	1,129	1,007	873

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,	2019	2018	2017
Net Earnings	\$ 24,382	\$ 23,849	\$ 21,557
Other comprehensive income (loss):			
Foreign currency translation adjustment	(802)	(1,075)	1,616
Unrealized gain (loss) on cash flow hedge	(1,159)	907	1,544
Amortization of gain on cash flow hedge	(102)	-	-
Income taxes related to items of other comprehensive income	465	(263)	(590)
Other comprehensive income (loss), net of tax	(1,598)	(431)	2,570
Comprehensive Income	\$ 22,784	\$ 23,418	\$ 24,127

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,	2019	2018	2017
Cash Flows From Operating Activities			
Net earnings	\$ 24,382	\$ 23,849	\$ 21,557
Non-cash items included in net earnings:			
Depreciation of property, plant and equipment	5,433	4,491	4,342
Amortization of intangible assets	4,531	3,433	3,776
Amortization of deferred instrument costs	-	764	972
Stock-based compensation	3,251	3,402	3,381
Goodwill impairment charge	-	-	6,628
Deferred income taxes	(817)	(300)	1,474
Losses on dispositions of long-lived assets	632	-	-
Change in the following, net of acquisition:			
Accounts receivable	(2,314)	(4,447)	(1,211)
Inventories	3,841	(1,142)	3,467
Prepaid expenses and other current assets	(2,044)	323	1,225
Accounts payable and accrued expenses	(2,315)	4,124	(3,151)
Income taxes payable	1,793	(524)	(384)
Other, net	(542)	810	(721)
Net cash provided by operating activities	35,831	34,783	41,355
Cash Flows From Investing Activities			
Purchase of property, plant and equipment	(3,797)	(4,201)	(4,467)
Disposals of property, plant and equipment	669	-	-
Acquisition of GenePOC business	(45,324)	-	-
Net cash used for investing activities	(48,452)	(4,201)	(4,467)
Cash Flows From Financing Activities			
Dividends paid	(10,612)	(21,170)	(24,266)
Proceeds from revolving credit facility	75,824	-	-
Payment of debt issuance costs	(489)	-	-
Payments on term loan	(50,250)	(4,500)	(3,750)
Proceeds and tax benefits from exercises of stock options	787	187	303
Payment of acquisition consideration	-	(2,110)	-
Net cash provided by (used for) financing activities	15,260	(27,593)	(27,713)
Effect of Exchange Rate Changes on Cash and Equivalents and Restricted Cash	(1,005)	(298)	671
Net Increase in Cash and Equivalents and Restricted Cash	1,634	2,691	9,846
Cash and Equivalents and Restricted Cash at Beginning of Period	60,763	58,072	48,226
Cash and Equivalents and Restricted Cash at End of of Period	\$ 62,397	\$ 60,763	\$ 58,072
Cash and Equivalents	\$ 62,397	\$ 59,763	\$ 57,072
Restricted Cash	-	1,000	1,000
Cash and Equivalents and Restricted Cash at End of Period	\$ 62,397	\$ 60,763	\$ 58,072

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

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,	2019	2018
Assets		
Current Assets:		
Cash and equivalents	\$ 62,397	\$ 59,763
Accounts receivable, less allowances of \$537 and \$310, respectively	35,608	32,336
Inventories	39,617	41,993
Prepaid expenses and other current assets	7,139	4,961
Total current assets	144,761	139,053
Property, Plant and Equipment, at Cost:		
Land	982	1,160
Buildings and improvements	31,904	32,444
Machinery, equipment and furniture	64,155	50,606
Construction in progress	522	1,631
Subtotal	97,563	85,841
Less: accumulated depreciation and amortization	66,996	55,846
Net property, plant and equipment	30,567	29,995
Other Assets:		
Goodwill	89,241	54,637
Other intangible assets, net	60,243	23,113
Restricted cash	-	1,000
Deferred instrument costs, net	-	1,239
Fair value of interest rate swap	-	1,722
Deferred income taxes	156	130
Other assets	510	488
Total other assets	150,150	82,329
Total assets	\$ 325,478	\$ 251,377

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,	2019	2018
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	\$ 7,238	\$ 6,260
Accrued employee compensation costs	7,938	9,195
Other accrued expenses	3,758	3,133
Current portion of long-term debt	-	5,250
Income taxes payable	1,980	335
Total current liabilities	20,914	24,173
Non-Current Liabilities:		
Acquisition consideration	32,202	-
Post-employment benefits	2,500	2,646
Long-term debt	75,824	44,930
Long-term income taxes payable	549	441
Deferred income taxes	2,522	3,769
Total non-current liabilities	113,597	51,786
Commitments and Contingencies		
Shareholders' Equity:		
Preferred stock, no par value; 1,000,000 shares authorized; none issued	-	-
Common shares, no par value; 71,000,000 shares authorized, 42,712,296 and 42,399,962 issued, respectively	-	-
Additional paid-in capital	132,834	129,193
Retained earnings	63,108	49,602
Accumulated other comprehensive loss	(4,975)	(3,377)
Total shareholders' equity	190,967	175,418
Total liabilities and shareholders' equity	\$ 325,478	\$ 251,377

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
Balance at September 30, 2016	42,107	\$ 122,356	\$ 49,632	\$ (5,516)	\$ 166,472
Cash dividends paid - \$0.575 per share	-	-	(24,266)	-	(24,266)
Conversion of restricted share units and exercise of stock options	100	(129)	-	-	(129)
Stock compensation expense	-	3,381	-	-	3,381
Net earnings	-	-	21,557	-	21,557
Foreign currency translation adjustment	-	-	-	1,616	1,616
Hedging activity, net of tax	-	-	-	954	954
Balance at September 30, 2017	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
Balance at September 30, 2018	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	-
Balance at September 30, 2019	42,712	\$ 132,834	\$ 63,108	\$ (4,975)	\$ 190,967

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 and Euro 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.

Our investment portfolio includes the following components:

	September 30, 2019		September 30, 2018	
	Cash and Equivalents	Other	Cash and Equivalents	Other
Institutional money market funds	\$ 20,913	\$ -	\$ 20,421	\$ -
Cash on hand –				
Restricted	-	-	-	1,000
Unrestricted	41,484	-	39,342	-
Total	\$ 62,397	\$ -	\$ 59,763	\$ 1,000

- (f) **Inventories** - Inventories are stated at the lower of cost or market. 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 \$2,285 and \$1,971 at September 30, 2019 and 2018, 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 \$108, \$294 and \$394 in fiscal 2019, 2018 and 2017, 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. Following the fiscal 2018 restructuring and consolidation of separately-run businesses into two integrated global business units (see Note 3), at September 30, 2019 and September 30, 2018, 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 2019 and fiscal 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 fiscal 2018.

Similarly, during fiscal 2017, we performed quantitative assessments as of June 30, 2017 for each of our Americas Diagnostics, Bioline and Life Science-U.S. reporting units that existed at that time, noting the separate Magellan discussion below. 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 Americas Diagnostics, Bioline and Life Science-U.S. reporting units satisfied the quantitative assessment for fiscal 2017.

During the quarter ended June 30, 2017, the events described below occurred, indicating that impairment of the goodwill recorded as part of the Magellan acquisition had occurred.

On May 17, 2017, the FDA issued a field safety notice advising customers to discontinue use of Magellan’s lead testing systems with venous blood samples. This field safety notice was followed by product recall notices on May 25th and June 5th. Subsequent to the issuances of these field safety and product recall notices, the FDA completed an inspection of Magellan’s quality system, and issued its Form 483, Inspectional Observations, on June 29, 2017, which was expectedly followed by a Warning Letter issued on October 23, 2017. The Warning Letter requires periodic reporting on our remediation progress.

In light of these factors and their impacts, during the third quarter of fiscal 2017, it was determined that a potential impairment of goodwill recorded in connection with the acquisition of Magellan had occurred (i.e., a “triggering event”). With the assistance of an independent valuation firm, Magellan’s fair value was calculated via both market (comparable company) and income (discounted cash flows) approaches. Based upon these approaches, it was determined that the carrying value of the Magellan reporting unit did, in fact, exceed its fair value. As a result, an impairment charge of \$6,628, on both a pre-tax and after-tax basis, was recorded during the third quarter and is reflected as a separate operating expense line item within the accompanying Consolidated Statement of Operations for the year ended September 30, 2017. This quantitative assessment as of May 31, 2017 was supplemented by a qualitative assessment of Magellan’s goodwill as of June 30, 2017, with such assessment indicating that no additional impairment existed.

During fiscal 2019, goodwill increased \$34,604, reflecting 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. The decrease of \$289 in fiscal 2018 resulted solely 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, 2019 and 2018 is as follows.

	2019		2018	
	Gross Carrying Value	Accum. Amort.	Gross Carrying Value	Accum. Amort.
As of September 30,				
Manufacturing technologies, core products and cell lines	\$ 56,193	\$ 15,096	\$ 22,297	\$ 13,974
Tradenames, licenses and patents	14,494	6,094	8,647	5,267
Customer lists, customer relationships and supply agreements	24,274	14,110	24,461	13,051
Government grants	814	232	-	-
	\$ 95,775	\$ 35,532	\$ 55,405	\$ 32,292

The actual aggregate amortization expense for these intangible assets for fiscal 2019, 2018 and 2017 was \$4,531, \$3,433 and \$3,776, respectively. The estimated aggregate amortization expense for these intangible assets for each of the five succeeding fiscal years is as follows: fiscal 2020 - \$6,684, fiscal 2021 - \$5,490, fiscal 2022 - \$5,113, fiscal 2023 - \$5,100 and fiscal 2024 - \$5,096.

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. Aside from the Magellan matter noted above, no triggering events have been identified by the Company for fiscal 2019, 2018 or 2017.

(i) Revenue Recognition and Accounts Receivable -

Adoption of New Standard

On October 1, 2018, we adopted ASU No. 2014-09, *Revenue from Contracts with Customers*, using the modified retrospective transition method applied to those contracts that were not completed as of that date. Results for reporting periods beginning on or after October 1, 2018 are presented under the new guidance, while prior period amounts are not adjusted and continue to be reported in accordance with previously applicable guidance.

Upon adoption, we recorded a reduction of \$116 to the opening balance of retained earnings as of October 1, 2018. This adjustment is related to writing off the book value of clinical diagnostic testing instruments located at customers for which there is no contractual arrangement for the instrument to be returned to the Company. Instruments placed with customers under an agreement to return the instrument to the Company were reclassified to machinery and equipment. Prior to adoption of the new guidance, all instruments placed with customers were capitalized and amortized over an estimated three-year utilization period, with the net balance reflected as deferred instrument costs.

The following table summarizes the impact of the new revenue standard on our opening balance sheet:

	Balance at September 30, 2018	New Revenue Standard Adjustment	Balance at October 1, 2018
PROPERTY, PLANT AND EQUIPMENT			
Machinery, equipment and furniture	\$ 50,606	\$ 8,696	\$ 59,302
Accumulated depreciation and amortization	(55,846)	(7,611)	(63,457)
OTHER ASSETS			
Deferred instrument costs, net	1,239	(1,239)	-
NON-CURRENT LIABILITIES			
Deferred income taxes	(3,769)	38	(3,731)
SHAREHOLDERS' EQUITY			
Retained earnings	(49,602)	116	(49,486)

The adoption of this new standard had an immaterial impact on our reported total revenues and operating income, as compared to what would have been reported under the prior standard. Our accounting policies under the new standard were applied prospectively and are noted below following the discussion of Revenue Disaggregation.

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

	2019	2018	2017	2019 vs. 2018 Inc (Dec)	2018 vs. 2017 Inc (Dec)
Diagnostics-					
Americas	\$ 110,135	\$ 123,916	\$ 117,161	(11)%	6 %
EMEA	23,865	23,922	22,594	- %	6 %
ROW	2,682	2,616	3,766	3 %	(31)%
Total Diagnostics	136,682	150,454	143,521	(9)%	5 %
Life Science-					
Americas	19,443	21,080	20,265	(8)%	4 %
EMEA	29,157	24,715	22,365	18 %	11 %
ROW	15,732	17,322	14,620	(9)%	18 %
Total Life Science	64,332	63,117	57,250	2 %	10 %
Consolidated	\$ 201,014	\$ 213,571	\$ 200,771	(6)%	6 %

Revenue by Product Platform/Type

	2019	2018	2017	2019 vs. 2018 Inc (Dec)	2018 vs. 2017 Inc (Dec)
Diagnostics-					
Molecular assays	\$ 26,231	\$ 33,709	\$ 33,712	(22)%	- %
Immunoassays & blood chemistry assays	110,451	116,745	109,809	(5)%	6 %
Total Diagnostics	\$ 136,682	\$ 150,454	\$ 143,521	(9)%	5 %
Life Science-					
Molecular reagents	\$ 23,261	\$ 24,533	\$ 21,966	(5)%	12 %
Immunological reagents	41,071	38,584	35,284	6 %	9 %
Total Life Science	\$ 64,332	\$ 63,117	\$ 57,250	2 %	10 %

Revenue by Disease State (Diagnostics only)

	2019	2018	2017	2019 vs. 2018 Inc (Dec)	2018 vs. 2017 Inc (Dec)
Diagnostics-					
Gastrointestinal assays	\$ 68,977	\$ 78,803	\$ 79,022	(12)%	- %
Respiratory illness assays	26,622	28,911	23,881	(8)%	21 %
Blood chemistry assays	19,082	19,109	18,212	- %	5 %
Other	22,001	23,631	22,406	(7)%	5 %
Total Diagnostics	\$ 136,682	\$ 150,454	\$ 143,521	(9)%	5 %

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 title 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 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 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 have been 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

Our Revogene, Alethia and LeadCare 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 Meridian. 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 ASU No. 2014-09 but rather ASU 2016-02, *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 will be recognized at a point-in-time when control transfers.

Revenue allocated to the lease elements of these Reagent Rental arrangements represent approximately 2% of total revenue and are included as part of net revenues in our Consolidated Statements of Income.

- (j) **Fair Value Measurements** - Assets and liabilities are recorded at fair value in accordance with Accounting Standards Codification (“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 requires 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 the business of GenePOC in fiscal 2019. 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.

The following table provides information by level for financial assets and liabilities that are measured at fair value on a recurring basis, noting that there were no such items as of September 30, 2018:

As of September 31, 2019	Carrying Value	Fair Value Measurements Using Inputs Considered as		
		Level 1	Level 2	Level 3
Contingent consideration	\$ 27,200	\$ -	\$ -	\$ 27,200

In connection with the acquisition of the business of GenePOC and as set forth in Note 2, the Company is required to make contingent consideration payments of up to \$70,000, comprised of \$20,000 for achievement of product development milestones and up to \$50,000 for achievement of certain financial targets. The preliminary fair value for the contingent payments recognized upon the acquisition as part of the purchase accounting opening balance sheet totaled \$27,200. The preliminary fair value of the development milestone payments was estimated by discounting the probability-weighted contingent payments to present value. Assumptions used in the calculations were probability of success, duration of the earn-out and discount rate. The preliminary fair value of the financial performance target payments was determined using a Monte Carlo simulation-based model. Assumptions used in these calculations were 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. The liability is considered to be a Level 3 financial liability that is re-measured each reporting period.

- (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 6.
- (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 7(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

As described in Note 1(i) above, the Company adopted ASU No. 2014-09, *Revenue from Contracts with Customers*, on October 1, 2018 using the modified retrospective transition method.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*. The update addresses certain specific cash flows and their treatment, with the objective being to reduce the existing diversity in how the items are presented and classified within the statement of cash flows. The Company adopted this guidance in the first quarter of fiscal 2019, with the Condensed Consolidated Statements of Cash Flows reflecting such adoption, including the information related to restricted cash.

In January 2017, the FASB issued ASU 2017-01, *Clarifying the Definition of a Business*. Included within the standard is guidance designed to improve consistency in accounting for acquisition and disposition transactions. Specifically, the guidance sets forth a two-step process of determining if a "business" or an "asset" has, in fact, been acquired or disposed of. Adoption and implementation of this guidance was effective for the Company at the beginning of fiscal 2019, with the guidance being adhered to in accounting for the acquisition of the GenePOC business in June 2019. See Note 2 below.

In February 2018, the FASB issued ASU 2018-02, *Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, to address certain of the recent U.S. federal income tax legislation's impact on Accumulated Other Comprehensive Income ("AOCI"). The guidance specifically provides the option of reclassifying "stranded tax effects" related to the tax legislation from AOCI to retained earnings. The Company elected to adopt this guidance in the third quarter of fiscal 2019. An election was made to reclassify the income tax effects of the Tax Cuts and Jobs Act from AOCI to retained earnings, and an entry was made to increase AOCI and decrease retained earnings by \$148. The Company's accounting policy is to release the income tax effects in other comprehensive income as financial amounts are removed.

Pronouncements Issued but Not Yet Adopted as of September 30, 2019

In February 2016, the FASB issued ASU 2016-02, *Leases*, which amends the accounting guidance related to leases. These changes, which are designed to increase transparency and comparability among organizations for both lessees and lessors, include, among other things, requiring recognition of lease assets and liabilities on the balance sheet and disclosing key information about leasing arrangements. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2020, although early adoption is permitted. The Company adopted ASU 2016-02 effective October 1, 2019 using the modified retrospective method, which was applied to leases that existed or will be entered into on or after such date. The Company anticipates that as a result of such adoption, it will record to its balance sheet approximately \$6,000 of right-of-use assets and lease liabilities as of October 1, 2019.

- (r) **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) ***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 contemplates a maximum total consideration of up to \$120,000, which based upon the current preliminary valuation is estimated at a total fair value of approximately \$77,526. Pursuant to the purchase agreement, the maximum consideration is comprised of the following (noting that the current preliminary valuation values the contingent consideration identified in (ii) and (iii) below at an aggregate amount of approximately \$27,200):

- (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) 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.

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 as acquisition consideration within the non-current liabilities section of the accompanying Condensed Consolidated Balance Sheets. The holdback amounts are due to be settled in December 2020, following the 18-month anniversary of the transaction.

We utilized cash and equivalents on hand and proceeds drawn from our new \$125,000 revolving credit facility, which replaced our previous credit facility, to finance the acquisition. Proceeds from the new credit facility were also utilized to repay and settle the outstanding principal and interest due on our term loan (see Note 5). As a result of currently estimated total consideration exceeding the preliminary fair value of the net assets acquired, goodwill in the amount of \$34,582 was recorded in connection with this acquisition, which will be deductible for U.S. tax purposes ratably over 15 years. The goodwill results largely from Meridian's ability to market and sell GenePOC's technology and instrument platform through its established customer base and distribution channels.

Our Consolidated Statement of Operations for the year ended September 30, 2019 includes \$1,808 of acquisition-related costs related to the acquisition of the GenePOC business, which are reflected as operating expenses. Most of these costs relate to professional fees for attorneys, tax advisors and regulatory advisors during due diligence, and the preparation and negotiation of acquisition agreements.

The Company's fiscal 2019 consolidated results include \$341 of net revenues and \$3,848 of net loss from the GenePOC business since the date of acquisition. These results, which are reported as part of the Diagnostics segment, include \$1,204 of amortization of specific identifiable assets recorded in the opening balance sheet, including a license agreement, technology and a government grant.

Preliminary Purchase Price Allocation

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

	PRELIMINARY		
	June 3, 2019 (as initially reported)	Measurement Period Adjustments	June 3, 2019 (as adjusted)
Fair value of assets acquired -			
Accounts receivable	\$ 58	\$ (1)	\$ 57
Inventories	1,617	(106)	1,511
Other current assets	77	7	84
Property, plant and equipment	1,520	(96)	1,424
Goodwill	34,482	100	34,582
Other intangible assets (estimated useful life):			
License agreement (10 years)	5,990	-	5,990
Technology (15 years)	34,040	96	34,136
Government grant (1.33 years)	800	-	800
	78,584	-	78,584
Fair value of liabilities assumed -			
Accounts payable and accrued expenses	1,082	(24)	1,058
Total consideration paid (including contingent consideration currently estimated at \$27,200)	\$ 77,502	\$ 24	\$ 77,526

The allocation of the purchase price and estimated useful lives of property, plant and equipment, and intangible assets shown above remain preliminary and subject to adjustment, pending refinement and final completion of valuations, including but not limited to valuations of accounts receivable, inventory, other current assets, property, plant and equipment, and intangibles. Any modifications to the valuation of assets acquired and liabilities assumed will result in an adjustment to goodwill.

Pro Forma Information (Unaudited)

The following table provides the unaudited consolidated pro forma results for the periods presented as if the business of GenePOC had been acquired as of the beginning of fiscal 2018. 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,	2019	2018
Net Revenues	\$ 201,222	\$ 213,753
Net Earnings	\$ 16,093	\$ 9,407

These pro forma amounts have been calculated by including the results of GenePOC, and adjusting the combined results to give effect to the following, as if the acquisition had been consummated on October 1, 2017, together with the consequential tax effects thereon:

Year Ended September 30,	2019	2018
<u>Adjustments to Net Revenues</u>		
GenePOC pre-acquisition revenues	\$ 208	\$ 182
<u>Adjustments to Net Earnings</u>		
GenePOC pre-acquisition net loss	\$ (9,578)	\$ (12,775)
Pro forma adjustments:		
Meridian acquisition-related costs	1,808	-
GenePOC transaction-related costs	1,245	-
Expenses related to non-continuing personnel, locations or activities	1,576	2,552
Incremental depreciation and amortization	(2,344)	(3,499)
Incremental interest costs	(743)	(977)
Tax effects of pro forma adjustments	(253)	257
Total Adjustments to Net Earnings	\$ (8,289)	\$ (14,442)

Supplemental Cash Flow Information (Non-Cash Acquisition Consideration)

As noted above, non-cash acquisition consideration totaled \$32,200 as of September 30, 2019, which is comprised of: (i) \$5,000 of purchase price holdback; and (ii) \$27,200 contingent upon achievement of established milestones. No such items existed in fiscal 2018 or 2017.

(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. 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, as refinements to each business unit's cost structure continued to be made and the Company's previous CFO terminated employment.

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

	2019	2018
Severance, other termination benefits and related costs	\$ 2,046	\$ 5,012
Lease and other contract termination fees	54	353
Loss on fixed asset disposals and inventory scrap	528	225
Other	211	742
Total	\$ 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 have the compensation and benefits 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.

Accrued liabilities associated with the restructuring costs noted above are comprised of the following:

As of September 30,	2019	2018
Severance, other termination benefits and related costs	\$ 1,010	\$ 987
Lease and other contract termination fees	12	33
Other	114	6
Total	\$ 1,136	\$ 1,026

(4) Inventories

Inventories are comprised of the following:

As of September 30,	2019	2018
Raw materials	\$ 7,455	\$ 6,689
Work-in-process	11,504	12,098
Finished goods - instruments	935	1,191
Finished goods - kits and reagents	19,723	22,015
Total	\$ 39,617	\$ 41,993

(5) 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 credit facility, which expires in May 2024, makes available to the Company a revolving credit facility in an aggregate principal amount not to exceed \$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 3.78% on the credit facility in fiscal 2019. As of September 30, 2019, two draws have been made on the credit facility, resulting in an outstanding principal balance of \$75,824. 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, which had an outstanding balance of \$50,180 as of September 30, 2018; and (ii) along with cash on-hand, fund the GenePOC acquisition closing payment. In light of the recent execution date of the credit facility and interest being determined on a variable rate basis, the fair value of the borrowings under the credit facility at September 30, 2019 approximates the current carrying value reflected in the accompanying Consolidated Balance Sheet, as was also the case with the outstanding term loan balance as of September 30, 2018.

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, 2019, the Company is in compliance with all covenants.

In connection with the term loan repayment, 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 and which effectively converted the variable interest rate on the term loan to a fixed rate of 2.76%. 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 the interest rate swap reflected within the accompanying Consolidated Balance Sheet as of September 30, 2019. At September 30, 2018, there was an asset balance of \$1,722 related to the interest rate swap. The corresponding fair value amount 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 interest rate swap balance reflected within accumulated other comprehensive income at September 30, 2019 and September 30, 2018 totaled \$461 and \$1,722, respectively.

Supplemental Cash Flow Information (Interest Paid)

Cash paid for interest totaled \$1,405, \$1,487 and \$1,605 in fiscal 2019, 2018 and 2017, respectively.

(6) **Income Taxes**

(a) Earnings before income taxes, and the related provision for income taxes for the years ended September 30, 2019, 2018 and 2017 were as follows:

Year Ended September 30,	2019	2018	2017
Domestic	\$ 23,954	\$ 27,787	\$ 31,885
Foreign	7,603	2,593	4,544
Total earnings before income taxes	\$ 31,557	\$ 30,380	\$ 36,429
Provision (credit) for income taxes -			
Federal -			
Current	\$ 5,001	\$ 6,030	\$ 11,262
Temporary differences			
Fixed asset basis differences and depreciation	288	410	(181)
Intangible asset basis differences and amortization	(797)	(4,052)	(1,158)
Currently non-deductible expenses and reserves	241	1,206	884
Stock-based compensation	(109)	1,379	(635)
Net operating loss carryforwards utilized	69	61	1,831
Tax credit carryforwards utilized	-	181	67
Other, net	(169)	(148)	99
Subtotal	4,524	5,067	12,169
State and local	834	1,066	1,900
Foreign	1,817	398	803
Total income tax provision	\$ 7,175	\$ 6,531	\$ 14,872

(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,	2019	2018	2017			
Computed income taxes at statutory rate	\$ 6,627	21.0 % \$ 7,443	24.5 % \$ 12,750	35.0 %		
Increase (decrease) in taxes resulting from -						
State and local income taxes	577	1.8	982	3.2	1,093	3.0
U.S. tax law change	-	-	(2,655)	(8.7)	-	-
One-time repatriation tax	-	-	876	2.9	-	-
Foreign-Derived Intangible Income tax	(294)	(0.9)	-	-	-	-
Global Intangible Low Taxed Income tax	1,119	3.6	-	-	-	-
Foreign tax credit	(990)	(3.1)	(15)	-	(57)	(0.2)
Foreign tax rate differences	46	0.1	(104)	(0.3)	(281)	(0.8)
Qualified domestic production incentives	-	-	(550)	(1.8)	(1,012)	(2.8)
Uncertain tax position activity	126	0.4	(62)	(0.2)	134	0.4
Goodwill impairment charge	-	-	-	-	2,320	6.4
Valuation allowance	106	0.3	(40)	(0.1)	-	-
Stock-based compensation	(33)	(0.1)	447	1.4	-	-
Other, net	(109)	(0.4)	209	0.6	(75)	(0.2)
	\$ 7,175	22.7 % \$ 6,531	21.5 % \$ 14,872	40.8 %		

On December 22, 2017, the United States enacted tax reform legislation commonly known as the Tax Cuts and Jobs Act (the “tax reform act”) and the following effects of the tax reform act are reflected within the consolidated financial statements for the year ended September 30, 2018: (i) a tax benefit of \$2,655, primarily from the re-measurement of deferred tax assets and liabilities; and (ii) \$876 of tax expense for the mandatory U.S. repatriation transition tax. The re-measurement of deferred tax assets and liabilities reflected the realization of temporary differences during fiscal 2018 at a transitional blended federal rate of 24.5%, with the remaining temporary differences being re-measured at the 21% federal rate. The tax reform act includes 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, 2019, the Company’s U.S. GILTI inclusion was \$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 tax liabilities were as follows:

As of September 30,	2019	2018
Deferred tax assets -		
Valuation reserves and non-deductible expenses	\$ 1,253	\$ 1,473
Stock compensation expense not deductible	2,158	2,033
Net operating loss and tax credit carryforwards	494	433
Basis difference in equity-method investee	302	302
Inventory basis differences	289	383
Other	125	(530)
Subtotal	4,621	4,094
Less valuation allowance	(408)	(302)
Deferred tax assets	4,213	3,792
Deferred tax liabilities -		
Fixed asset basis differences and depreciation	(2,205)	(1,913)
Intangible asset basis differences and amortization	(4,374)	(5,518)
Deferred tax liabilities	(6,579)	(7,431)
Net deferred tax liabilities	\$ (2,366)	\$ (3,639)

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 \$231 and \$263, respectively, as of September 30, 2019. At September 30, 2018, such deferred tax assets totaled \$303 and \$130, respectively. The operating loss carryforwards in Canada expire in 2039, with such carryforwards in the other foreign jurisdictions having 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 totaled \$366, \$2,443 and \$914, respectively, at September 30, 2019. The use of the federal and state losses is limited by the change of ownership provisions of the Internal Revenue Code.

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 \$4,213 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, 2019 and September 30, 2018 related to such positions was \$383 and \$262, respectively, of which \$309 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 2019 and 2018, such penalties and interest totaled approximately \$34 and \$84, respectively. We had

approximately \$128 accrued for the payment of interest and penalties at September 30, 2019 compared to \$162 accrued at September 30, 2018. 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:

	2019	2018
Unrecognized income tax benefits at beginning of year	\$ 262	\$ 517
Additions for tax positions of prior years	83	-
Reductions for tax positions of prior years	(100)	-
Additions for tax positions of current year	138	-
Tax examination and other settlements	-	(161)
Expiration of statute of limitations	-	(94)
Unrecognized income tax benefits at end of year	\$ 383	\$ 262

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 and Italy. In the U.S., open tax years are fiscal 2016, fiscal 2017 and fiscal 2018. In countries outside the U.S., open tax years generally range from fiscal 2014 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 \$7,840, \$6,555 and \$12,613 in fiscal 2019, 2018 and 2017, respectively.

(7) **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 (3% through December 31, 2016). Our discretionary and matching contributions to the plan amounted to approximately \$1,979, \$2,118 and \$1,912, during fiscal 2019, 2018 and 2017, respectively.
- (b) **Stock-Based Compensation Plans** - During fiscal 2019, 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, 2019, we have granted 1,292 and 2,051 shares under the 2004 Plan and 2012 Plan, respectively, thereby resulting in a remaining authorized limit of 2,657 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 2017 through 2019, we granted, in the aggregate for the three-year period, approximately 1,100 restricted share units (with weighted-average grant date fair values of \$16.93 per share in fiscal 2017, \$14.65 per share in fiscal 2018 and \$18.66 per share in fiscal 2019) to certain employees. The units granted in fiscal 2019 were generally time-vested restricted share units vesting in total on the third anniversary of the grant date. During fiscal 2018 and 2017, 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 each fiscal period, the targets for each fiscal period were not met and the performance-based portion of these restricted share units granted have been cancelled.

During fiscal 2017 in connection with his Amended and Restated Employment Agreement, we also 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 \$19.09 per share), with each respective grant to be earned only if specified revenue and earnings per share targets were achieved for fiscal 2017. As a result of the performance targets not being achieved, these restricted share units have been cancelled.

Additionally, during fiscal 2018 in connection with the October 9, 2017 employment of the Company's current CEO, Mr. Jack Kenny, 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 432 restricted share units remain outstanding as of September 30, 2019, with a weighted-average grant date fair value of \$17.17 per share, a weighted-average remaining vesting period of 1.53 years and an aggregate intrinsic value of \$4,096. The weighted-average grant date fair value of the approximate 285 restricted share units that vested during fiscal 2019 was \$17.34 per share.

The amount of stock-based compensation expense reported was \$3,251, \$3,402 and \$3,381 in fiscal 2019, 2018 and 2017, respectively. The fiscal 2019 expense is comprised of \$542 related to stock options and \$2,709 related to restricted share units; the fiscal 2018 expense is comprised of \$793 related to stock options and \$2,609 related to restricted share units; and the fiscal 2017 expense is comprised of \$662 related to stock options and \$2,719 related to restricted share units. The total income tax benefit recognized in the income statement for these stock-based compensation arrangements was \$572, \$303 and \$861, for fiscal 2019, 2018 and 2017, respectively. As of September 30, 2019, we expect future stock compensation expense for unvested options and unvested restricted share units to total \$240 and \$2,756, respectively, which will be recognized during fiscal years 2020 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 2019, 2018 and 2017, we recorded \$127, \$106 and \$106, respectively, in stock compensation expense to adjust estimated forfeiture rates to actual, noting that total fiscal 2019 stock compensation expense 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,	2019	2018	2017
Risk-free interest rates	2.99 %	2.10 %	1.34 %
Dividend yield	3.3 %	3.3 %	4.1 %
Life of option	6.51 yrs.	6.47 yrs.	6.44 yrs.
Share price volatility	29 %	30 %	27 %
Forfeitures (by employee group)	0%-16%	0%-16%	0%-19%

A summary of the status of our stock option plans as of September 30, 2019, and changes during the year ended September 30, 2019, 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	1,095	\$ 17.56		
Grants	77	16.07		
Exercises	(30)	15.13		
Forfeitures	(52)	15.03		
Cancellations	(100)	20.48		
Outstanding end of period	990	\$ 17.36	6.37	\$ 1
Exercisable end of period	782	\$ 17.99	5.86	\$ -

A summary of the status of our nonvested options as of September 30, 2019, and changes during the year ended September 30, 2019, is presented below:

	Options	Weighted- Average Grant Date Fair Value
Nonvested beginning of period	389	\$ 3.24
Granted	77	3.61
Vested	(205)	3.39
Forfeitures	(52)	3.25
Nonvested end of period	209	\$ 3.24

The weighted average grant-date fair value of options granted was \$3.61, \$3.27 and \$2.65 for fiscal 2019, 2018 and 2017, respectively. The total intrinsic value of options exercised was \$62, \$2 and \$9 for fiscal 2019, 2018 and 2017, respectively. The total grant-date fair value of options that vested during fiscal 2019, 2018 and 2017 was \$735, \$580 and \$494, respectively.

Cash received from options exercised was \$443, \$183 and \$302 for fiscal 2019, 2018 and 2017, respectively. Tax expense recorded to additional paid-in capital from option exercises totaled \$0, \$0 and \$431 for fiscal 2019, 2018 and 2017, respectively.

In connection with Mr. Kenny's October 1, 2019 Amended and Restated Employment Agreement, in November 2019 we granted Mr. Kenny: (i) options to purchase 198 shares of common stock of the Company vesting on a pro rata basis over the three years ending October 1, 2022; and (ii) 99 restricted share units vesting 100% on October 1, 2022.

(8) Non-Current Liabilities

The Company has provided certain post-employment benefits to its former CEO, and these obligations total \$1,917 and \$1,864 at September 30, 2019 and 2018, respectively. In addition, we are required by the governments of certain foreign countries in which we operate to maintain a level of reserves for potential future severance indemnity. These reserves total \$702 and \$713 at September 30, 2019 and 2018, respectively.

(9) Reportable Segments and Major Concentration Data

Our reportable segments are Diagnostics and Life Science. The Diagnostics segment consists of manufacturing operations for infectious disease products in Cincinnati, Ohio and Quebec City, Canada, manufacturing operations for products detecting elevated lead levels in blood in Billerica, Massachusetts (near Boston), and the sale and distribution of diagnostics products domestically and abroad. 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 in Beijing, China to further pursue growing revenue opportunities in Asia.

Revenues from individual customers constituting 10% or more of consolidated net revenues are as follows:

Year Ended September 30,	2019	2018	2017
Customer A	\$ 18,096 (9)%	\$ 21,162 (10)%	\$ 22,397 (11)%
Customer B	\$ 17,350 (9)%	\$ 22,490 (11)%	\$ 17,825 (9)%

Accounts receivable from these two Diagnostics customers accounted for 13% and 12% of consolidated accounts receivable at September 30, 2019 and September 30, 2018, respectively. The Company's international revenues totaled approximately \$76,430, \$72,548 and \$66,682 in fiscal 2019, 2018 and 2017, respectively, and our three major product families – gastrointestinal, respiratory illnesses and blood chemistry – accounted for 57%, 59% and 60% of consolidated net revenues in fiscal 2019, 2018 and 2017, respectively. We currently purchase on a sole-source basis from a U.S. manufacturer the instruments on which our Alethia molecular testing platform operates. Additionally, two of our foodborne products sourced from another vendor accounted for 9%, 9% and 10% of third-party revenues for our Diagnostics segment in fiscal 2019, 2018 and 2017, respectively.

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,	2019	2018	2017
United States	\$ 105,648	\$ 120,555	\$ 114,494
Italy	10,898	10,398	9,004
France	2,442	2,353	1,845
United Kingdom	2,397	2,340	1,778
Puerto Rico	2,276	1,054	730
Japan	1,571	1,307	2,421
Belgium	1,465	1,711	1,507
Holland	1,411	1,454	1,290
Other countries	8,574	9,282	10,452
Total Diagnostics	\$ 136,682	\$ 150,454	\$ 143,521

Year Ended September 30,	2019	2018	2017
United States	\$ 18,936	\$ 20,468	\$ 19,595
Germany	12,664	8,108	7,406
China	8,460	8,347	5,898
United Kingdom	4,714	5,201	5,579
Spain	4,415	4,187	3,209
Australia	3,461	3,631	4,002
France	2,200	2,040	1,792
Japan	1,624	1,932	1,375
Italy	1,357	971	700
South Korea	1,134	2,044	2,308
Other countries	5,367	6,188	5,386
Total Life Science	\$ 64,332	\$ 63,117	\$ 57,250

In locations outside the U.S., the Company's identifiable assets were concentrated as follows at the end of most recent fiscal years:

As of September 30, 2019: U.K – \$22,963; Germany – \$7,141; Italy – \$7,557; and Australia – \$1,392

As of September 30, 2018: U.K – \$14,816; Germany – \$7,706; Italy – \$7,334; and Australia – \$3,543

Segment information for the interim periods is as follows:

	Diagnostics	Life Science	Corporate ⁽¹⁾	Eliminations ⁽²⁾	Total
Fiscal 2019					
Net revenues -					
Third-party	\$ 136,682	\$ 64,332	\$ -	\$ -	\$ 201,014
Inter-segment	462	361	-	(823)	-
Operating income	22,399	20,572	(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
Fiscal 2018					
Net revenues -					
Third-party	\$ 150,454	\$ 63,117	\$ -	\$ -	\$ 213,571
Inter-segment	392	397	-	(789)	-
Operating income	32,569	13,799	(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

Fiscal 2017					
Net revenues -					
Third-party	\$ 143,521	\$ 57,250	\$ -	\$ -	\$ 200,771
Inter-segment	389	537	-	(926)	-
Operating income	34,124	14,086	(11,097)	269	37,382
Depreciation and amortization	7,037	2,053	-	-	9,090
Capital expenditures	2,554	1,913	-	-	4,467
Goodwill	35,213	19,713	-	-	54,926
Other intangible assets, net	24,973	1,731	-	-	26,704
Total assets	180,226	69,938	-	(387)	249,777

⁽¹⁾ Includes Restructuring and Selected Legal Costs of \$2,596, \$7,779 and \$762 in fiscal years 2019, 2018 and 2017, respectively.

⁽²⁾ Eliminations consist of inter-segment transactions.

A reconciliation of segment operating income to consolidated earnings before income taxes for the years ended September 30, 2019, 2018 and 2017 is as follows:

Year Ended September 30,	2019	2018	2017
Segment operating income	\$ 43,072	\$ 46,660	\$ 48,479
Corporate expenses	(10,373)	(15,076)	(11,097)
Interest income	681	418	171
Interest expense	(1,945)	(1,520)	(1,642)
Other, net	122	(102)	518
Consolidated earnings before income taxes	\$ 31,557	\$ 30,380	\$ 36,429

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

(10) Commitments and Contingencies

- (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 84% 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 \$2,107, \$2,579 and \$2,600 for the fiscal years ended September 30, 2019, 2018 and 2017, respectively.
- (b) **Purchase Commitments** - Excluding the operating lease commitments reflected in Note 10(c) below, we have purchase commitments primarily for inventory and service items as part of the normal course of business. Commitments made under these obligations are \$14,203 for fiscal 2020 and \$792 for fiscal 2021 through fiscal 2023. No purchase commitments have been made beyond fiscal 2023.
- (c) **Operating Lease Commitments** - 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. Amounts charged to expense under operating leases were \$2,372, \$2,457 and \$2,140 for fiscal 2019, 2018 and 2017, respectively. Operating lease commitments for each of the five succeeding fiscal years are as follows: fiscal 2020 - \$1,528; fiscal 2021 - \$1,451; fiscal 2022 - \$1,293; fiscal 2023 - \$967; and fiscal 2024 - \$712.

- (d) **Acquisition Price Holdback and Contingent Consideration** - Pursuant to the purchase agreement related to the June 3, 2019 acquisition of the business of GenePOC, Meridian's maximum remaining consideration to be paid totals \$75,000. As detailed in Note 2, this amount is comprised of: (i) a \$5,000 purchase price holdback; and (ii) up to \$70,000 of payments contingent upon the achievement of certain product development milestones and financial performance targets, the preliminary valuation of which totals approximately \$27,200 as of September 30, 2019.
- (e) **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. See Item 3. "Legal Proceedings" for a discussion of the status of these selected legal matters.
- (f) **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, 2019 or September 30, 2018.

(11) **Quarterly Financial Data (Unaudited)**

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

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	31,572	29,338	28,259	29,156
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	-	-

For the Quarter Ended in Fiscal 2018	December 31	March 31	June 30	September 30
Net revenues	\$ 52,283	\$ 56,451	\$ 51,737	\$ 53,100
Gross profit	32,010	34,569	31,962	32,156
Net earnings	6,302	5,288	6,825	5,434
Basic earnings per common share	0.15	0.12	0.16	0.13
Diluted earnings per common share	0.15	0.12	0.16	0.13
Cash dividends per common share	0.125	0.125	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, 2019, an evaluation, excluding the internal controls of certain net assets of the business of GenePOC acquired in June 2009, 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, 2019. 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, 2019.

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

The following information is provided pursuant to Item 5.03 of Form 8-K.

Effective November 26, 2019 the Company’s Board of Directors adopted an amendment to its Amended and Restated Code of Regulations for the purpose of facilitating virtual meetings of shareholders.

The following sentence was added to Article II, Section 3 (Place of Meetings): “The Board of Directors may, in its sole discretion, determine that any meeting shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Ohio law.”

The Amended and Restated Code of Regulations including this amendment is included as Exhibit 3.1 to this Annual Report on Form 10-K, and is incorporated herein by reference. The foregoing summary of the amendment is qualified in its entirety by reference to the specific provisions of the Amended and Restated Code of Regulations.

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 29, 2020 (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 meridiabioscience.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 (Filed herewith)
3.2	Amended and Restated Code of Regulations (Filed herewith)
4.1	Description of Securities (Filed herewith)
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*	2004 Equity Compensation Plan, amended and restated 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*	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)
10.7*	Form of Time-Based Restricted Share Unit Award Agreement (Incorporated by reference to Meridian's Annual Report on Form 10-K for the Fiscal Year Ended September 30, 2018)
10.8*	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)
10.9**	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)

10.10**	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)
10.11**	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)
10.12*	Consulting Agreement between Meridian Bioscience, Inc. and Melissa Lueke dated December 10, 2018 (Incorporated by reference to Meridian's Form 8-K filed with the Securities and Exchange Commission on December 12, 2018)
10.13*	Cash-Based Incentive Compensation Plan for Fiscal Year 2019 (Incorporated by reference to Meridian's Form 8-K filed with the Securities and Exchange Commission on December 12, 2018)
10.14*	Separation Agreement and General Release Agreement between Meridian Bioscience, Inc. and Lawrence Baldini dated April 26, 2019 (Incorporated by reference to Meridian's Form 8-K filed with the Securities and Exchange Commission on April 30, 2019)
10.15*	Separation Agreement and General Release between Meridian Bioscience, Inc. and Eric Rasmussen dated June 21, 2019 (Incorporated by reference to Meridian's Form 8-K filed with the Securities and Exchange Commission on June 25, 2019)
14	Code of Ethics (Incorporated by reference to Meridian's Annual Report on Form 10-K for the Fiscal Year Ended September 30, 2003)
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 26, 2019

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 26, 2019
<u>/s/ Bryan T. Baldasare</u> Bryan T. Baldasare	Executive Vice President, Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	November 26, 2019
<u>/s/ David C. Phillips</u> David C. Phillips	Chairman of the Board	November 26, 2019
<u>/s/ James M. Anderson</u> James M. Anderson	Director	November 26, 2019
<u>/s/ Dwight E. Ellingwood</u> Dwight E. Ellingwood	Director	November 26, 2019
<u>/s/ John C. McIlwraith</u> John C. McIlwraith	Director	November 26, 2019
<u>/s/ John M. Rice, Jr.</u> John M. Rice, Jr.	Director	November 26, 2019
<u>/s/ Catherine A. Sazdanoff</u> Catherine A. Sazdanoff	Director	November 26, 2019
<u>/s/ Felicia Williams</u> Felicia Williams	Director	November 26, 2019

SCHEDULE II
Meridian Bioscience, Inc.
and Subsidiaries

Valuation and Qualifying Accounts
(Dollars in thousands)
Years Ended September 30, 2019, 2018 and 2017

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Deductions	Other (a)	Balance at End of Period
Year Ended September 30, 2019:					
Allowance for doubtful accounts	\$ 310	\$ 347	\$ (100)	\$ (20)	\$ 537
Inventory realizability reserves	1,971	774	(448)	(12)	2,285
Valuation allowances – deferred taxes	302	106	-	-	408
Year Ended September 30, 2018:					
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
Year Ended September 30, 2017:					
Allowance for doubtful accounts	\$ 334	\$ 90	\$ (134)	\$ 17	\$ 307
Inventory realizability reserves	2,680	35	(661)	5	2,059
Valuation allowances – deferred taxes	342	-	-	-	342

(a) Balances reflect the effects of currency translation.

