

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-K

Annual Report Under Section 13 or 15(d) of The Securities Exchange Act of 1934

For The Fiscal Year Ended May 31, 2020 or

Transition Report Under Section 13 or 15(d) of The Securities Exchange Act Of 1934

For The Transition Period From \_\_\_\_\_ To \_\_\_\_\_

Commission File Number: 001-37863

**BIOMERICA, INC.**

(Exact Name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
Incorporation of organization)

**95-2645573**  
(I.R.S. Employer  
Identification No.)

**17571 Von Karman Avenue, Irvine, CA**  
(Address of principal executive offices)

**92614**  
(Zip Code)

REGISTRANT'S TELEPHONE NUMBER:  
**(949) 645-2111**

Securities registered under Section 12(b) of the Exchange Act:

**None**

Securities registered under Section 12(g) of the Exchange Act:

(Title of each class)  
**COMMON STOCK, PAR VALUE \$0.08**

(Name of each exchange on which registered)  
NASDAQ Capital Market

(Trading symbol)  
BMRA

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

Yes  No

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

Yes  No

Note - Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Exchange Act from their obligations under those Sections.

Indicate by check whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation (paragraph 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

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

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Smaller Reporting Company

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

Yes  No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter (based upon 7,747,639 shares held by non-affiliates and the closing price of \$3.02 per share for Common Stock in the over-the-counter market as of November 30, 2019): \$23,397,870.

Indicate the number of shares outstanding of each of the registrant's common stock, par value \$0.08, outstanding as of August 31, 2020:

11,752,589.

DOCUMENTS INCORPORATED BY REFERENCE: Part III contains information incorporated by reference to the Company's proxy statement for its 2020 Annual Meeting of Stockholders, which will be filed not later than 120 days after the end of the Company's fiscal year ended May 31, 2020. The Exhibit Index incorporates by reference various documents previously filed with the Securities and Exchange Commission.

## PART I

### ITEM 1. BUSINESS

#### BUSINESS OVERVIEW

##### THE COMPANY

Biomerica, Inc. ("Biomerica", the "Company", "we", "us" or "our") was incorporated in Delaware in September 1971 as Nuclear Medical Systems, Inc., and later changed its name to Biomerica, Inc. The Company has two wholly owned subsidiaries, Biomerica de Mexico, which is used for assembly/manufacturing and BioEurope GmbH, which acts as a distributor of Biomerica products in certain markets.

We are a global biomedical technology company that develops, patents, manufactures and markets advanced diagnostic and therapeutic products used at the point-of-care (in home and in physicians' offices) and in hospital/clinical laboratories for detection and/or treatment of medical conditions and diseases. The Company's products are designed to enhance the health and well-being of people, while reducing total healthcare costs.

Our primary focus is the research and development of revolutionary, patented diagnostic guided therapy ("DGT") products to treat gastrointestinal diseases, such as irritable bowel syndrome ("IBS"), and other inflammatory diseases. These products are directed at chronic inflammatory illnesses that are widespread and common, and as such address very large markets. If these DGT products prove effective in their clinical trials, and are ultimately cleared for sale by the U.S. Food and Drug Administration ("FDA"), we believe the revenues potential to the Company is significant.

Our medical diagnostic products are sold worldwide in two markets: 1) clinical laboratories and 2) point-of-care (physicians' offices and over-the-counter drugstores). The diagnostic test kits are used to analyze blood, urine, or fecal specimens from patients in the diagnosis of various diseases and other medical complications, by measuring or detecting the existence and/or level of specific bacteria, hormones, antibodies, antigens or other substances, which may exist in a patient's body, stools, or blood, often in extremely small concentrations.

Due to the global 2019 SARS-CoV-2 novel coronavirus ("COVID-19") pandemic, in March 2020 we began redirecting and focusing a majority of our resources to develop, test, validate, seek regulatory approval for, and sell diagnostic products that indicate if a person has been infected by COVID-19. These diagnostic tests use a patient's blood sample to detect if the patient has certain antibodies to COVID-19 that were created as part of their body's immune response to a COVID-19 infection, even if the infection was asymptomatic. During the fourth quarter of fiscal 2020 we began marketing and selling outside of the U.S. a disposable rapid finger-prick blood test, which detects COVID-19 IgG/IgM antibodies within 10 minutes. This test is designed to be performed by trained professionals anywhere (e.g. airports, schools, work, pharmacies and doctors' offices). Following fiscal 2020 year-end we submitted to the FDA an application under an Emergency Use Authorization ("EUA") to sell in the U.S. a lab-scale, high throughput ELISA COVID-19 antibody test kit that would be sold to labs and hospitals to perform COVID-19 antibody testing. The Company also anticipates selling this test kit outside of the U.S. under a CE Mark (European Conformity). Initial sales for this product are expected during the Company's second quarter of fiscal 2021 upon EUA clearance. The Company manufactures this COVID-19 ELISA test on its automated equipment at the Company's California facility that is also used to produce serology antibody tests for other diseases.

Aside from the current focus on COVID-19 products in research, development and clinical trials, the products we continue to sell are primarily focused on gastrointestinal diseases, food intolerances, diabetes and certain esoteric tests. These diagnostic test products utilize immunoassay technology. Our products are CE marked and/or sold for diagnostic use where they are registered by each country's regulatory agency. In addition, some products are cleared for sale in the U.S. by the FDA.

Technological advances in medical diagnostics have made it possible to perform diagnostic tests within the home and the physician's office (the point-of-care), rather than in the clinical laboratory. One of our objectives has also been to develop and market rapid diagnostic tests that are accurate, employ easily obtained specimens, and are simple to perform without instrumentation. Our over-the-counter (home use) and professional use (doctor's office, clinics, etc.) rapid diagnostic products help to manage existing medical conditions and may save lives through early detection and prompt diagnosis. Typically, tests of this kind required the services of medical technologists and sophisticated instrumentation. Further, results are often not available until at least the following day. We believe that rapid point-of-care tests can be as accurate as laboratory tests when used properly, require limited to no instrumentation, give reliable results in minutes and can be performed with confidence in the home or the physician's office.

Biomerica maintains its headquarters in Irvine, California, where it houses administration, product development, sales and marketing, customer services and its primary manufacturing operations. Biomerica also maintains manufacturing and assembly operations in Mexicali, Mexico, in order to reduce the cost of manufacturing and compete more effectively worldwide. The Company expends considerable funds in research and development of certain new products that diagnose and, in certain cases, are designed to be used as a therapy for several major medical diseases. These products are both internally developed and licensed from others. We employ experienced and highly trained technical personnel (including Ph.D.'s and scientists) to develop new products and evaluate and implement technology transfer activities. Our technical staff, many of whom have been previously employed at large diagnostic manufacturing companies, has extensive industry experience. We also rely on our Scientific Advisory Board of leading medical doctors and clinicians to assist in guiding our clinical studies and product development.

Additional information about Biomerica is available on our website at [www.biomerica.com](http://www.biomerica.com). The content on any website referred to in this Form 10-K is not a part of or incorporated by reference in this Form 10-K unless expressly noted. Our Annual Report on Form 10-K, Quarterly Reports on Forms 10-Q, Current Reports on Forms 8-K, Proxy Statements and all other filings we make with the Securities and Exchange Commission ("SEC") are available on our website, free of charge, as soon as reasonably practical after we file them with or furnish them to the SEC and are also available online at the SEC's website at [www.sec.gov](http://www.sec.gov).

## **PRODUCTION**

Most of our diagnostic test kits are manufactured and/or assembled at our facilities in Irvine, California and in Mexicali, Mexico. We established our manufacturing facility in Mexicali, Mexico in fiscal 2003 and moved a significant portion of our diagnostic packaging and assembly to that facility.

Production of diagnostic tests can involve formulating component antibodies and antigens in specified concentrations, attaching a tracer to the antigen, filling components into vials, packaging and labeling. We continually engage in quality control procedures to assure the consistency and quality of our products and to comply with applicable FDA and international regulations.

Our manufacturing operations and facilities are regulated by the FDA Good Manufacturing Practices for medical devices. We have an internal quality department that monitors and evaluates product quality and output. We also have an internal Quality Systems department whose goal is to ensure that our operating procedures are in compliance with current FDA, CE Mark and International Organization for Standardization ("ISO") regulations. We either produce our own antibodies and antigens or purchase these materials from qualified vendors. We have alternate, approved sources for most critical raw materials and are working to procure alternate sources for the few that we do not have.

## **RESEARCH AND DEVELOPMENT**

We are currently focused on developing several COVID-19 diagnostic tests, as discussed in this section below, and developing and pursuing the regulatory approval of two tests for the gastrointestinal market. Our increase in research and development spending is due to our focus on these tests and outside clinical studies intended to demonstrate the feasibility of FDA clearance for such tests. The Company also utilizes technical personnel, with Ph.D. and other degrees and extensive experience in development and production of health diagnostic tests, to conduct other development activities and improve existing products, as well as explore potential new technologies that the Company may wish to develop and commercialize. Research and development expenses include the costs of materials, supplies, personnel, consultants, legal fees, facilities, outside clinical trial sites and equipment as well as outside contract services. Consolidated research and development expenses incurred by Biomerica for the years ended May 31, 2020 and 2019 aggregated \$1,910,209, and \$1,679,098, respectively. As Biomerica begins to validate and commercialize additional key products that address diseases with large market opportunities, research and development expenses are expected to increase during upcoming quarters.

The Company has developed a unique diagnostic guided therapy that is designed to allow physicians to identify patient-specific foods (e.g. pork, milk, onions, sugar, chickpeas, etc.), that when removed from the diet, may alleviate or improve an individual's symptoms of IBS. This product is called InFoods® IBS and is currently in clinical studies at the Mayo Clinics in Florida and Arizona, Beth Israel Deaconess Medical Center Inc., a Harvard Medical School Teaching Hospital, University of Texas Health Science Center at Houston, Houston Methodist and at the University of Michigan. The United States Patent and Trademark Office ("USPTO") has issued the Company two patents with broad claims that protect the InFoods® IBS product. Patents have also been issued in the countries of Japan and Korea. Additional patents for this product have been filed in the U.S. and in other countries. We are also developing, and have filed patents for other diseases that utilize the InFoods® DGT technology platform which include: Functional Dyspepsia, Crohn's Disease, Ulcerative Colitis, Gastroesophageal reflux disease ("GERD"), Migraine Headaches, and Osteoarthritis.

We are also in clinical studies to evaluate the performance of our new and proprietary *Helicobacter pylori* (“H. pylori”) test. The clinical studies are being conducted at the University of Southern California (“USC”), a European University and several other U.S. locations. The Company is working to complete the analytical studies needed to prepare for submission to the FDA and plans to utilize a 510(k) clearance pathway for this test. Biomerica’s test is designed to provide highly accurate sensitivity and specificity for H. pylori testing and for monitoring of treatment.

We are planning to pursue a de novo 510(k) clearance with the FDA rather than a Premarket Approval Application (“PMA”) for the InFoods® IBS product. De novo clearance is typically faster and less expensive than the PMA route, which is the most stringent type of device marketing application required by the FDA. We are planning to submit the H. pylori product using a 510(k) application if validation testing proves effective.

Since March 2020, we have dedicated a majority of resources to develop, test, validate, seek regulatory approval for, and sell diagnostic products that indicate if a person has been infected by COVID-19. These diagnostic tests use a patient’s blood sample to determine if the patient has certain antibodies to COVID-19 that were created as part of their body’s immune response to a COVID-19 infection. Following the end of fiscal 2020, we have also dedicated resources to developing a COVID-19 antigen test that is intended to use a patient’s nasal or saliva sample to determine if the patient has a current and ongoing COVID-19 infection. We submitted to the FDA an application under and Emergency Use Authorization (“EUA”) to sell in the U.S. a lab-scale high throughput ELISA COVID-19 antibody test kit that would be sold to labs and hospitals to perform COVID-19 antibody testing. As part of this test we developed and are testing a whole blood collection system to allow simple whole blood sample collection from a finger stick. We anticipate that upon FDA EUA clearance, this collection system will be marketed in the U.S. and internationally. We also are developing and working on other COVID-19 test technologies.

Since the beginning of March 2020, the majority of our research and development resources and our regulatory clearance resources have been focused on developing, validating and registering for sale both point of care (finger-prick rapid tests), and ELISA high throughput laboratory COVID-19 antibody tests in that our primary InFoods product, InFoods® IBS, is now in clinical trials and as such requires limited research and development or regulatory resources. We expect that the majority of these Company resources will continue to be used in the foreseeable future for the development of COVID-19 tests.

## **MARKETS AND METHODS OF DISTRIBUTION**

Biomerica has approximately 400 current customers for its diagnostic business, of which approximately 75 are foreign distributors, 40 are domestic distributors and the balance are primarily domestic hospital and clinical laboratories, medical research institutions, medical schools, pharmaceutical companies, chain drugstores, wholesalers, physicians’ offices and e-commerce customers.

We employ a director of sales and marketing for Europe and South America who is headquartered in Germany. She has 23 years of experience selling and marketing diagnostic and life science products across multiple diagnostics technologies and disciplines. She possesses broad international business experience, with communication skills in German, English, Spanish, French and Portuguese, and scientific and technical understanding of gastrointestinal diagnostic products. She also has strong relationships with key strategic entities in Europe, Eastern Europe, Latin America, Canada and the U.S. who we believe will help Biomerica add new distributors for existing products, and add new product-lines for future distribution by the Company.

We rely on affiliated and unaffiliated distributors, advertising in medical and trade journals, exhibitions at trade shows, direct mailings and an internal sales staff to market our diagnostic products. We target two main markets: (a) clinical laboratories and (b) point-of-care testing (physicians’ offices and over-the-counter drug stores).

Subsequent to February 29, 2020, the Company’s fiscal third quarter end, the Coronavirus pandemic, which started in China at the end of 2019, has spread throughout the world, including the U.S. The impact it will have on the Company’s operations is unknown at this time. The Company has faced disruptions in certain of the following areas, and may face further challenges from supply chain disruptions, loss of contracts and/or customers, closure of the Company’s manufacturing or distribution facilities or of the facilities of the Company’s partners and customers, travel, shipping and logistical disruptions, government responses of all types, international business risks in countries where the Company makes and/or sells its products, loss of human capital or personnel at the Company, its partners and its customers, interruptions of production, customer credit risk, and general economic calamities. These pandemic related disruptions can materially negatively impact the Company’s operations and financial performance and may continue to have significant material negative impacts on the Company.

On March 17, 2020, the Company announced it had commenced shipping initial samples of its COVID-19 IgG/IgM Rapid Test (qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to SARS-CoV-2 in whole blood or serum) to countries outside the U.S. for evaluation. The test is a finger-prick blood test that is designed to show results in approximately 10 minutes and can be performed by trained professionals at any location, including airports, schools, work, pharmacies and doctors' offices. On March 16, 2020, the Company commenced shipping and fulfilling commercial orders for this Rapid Test to customers outside of the U.S. primarily through distributors. The Company has also filed for EUA clearance with the FDA to sell its ELISA COVID-19 test kit in the U.S. Once approved, we will market this ELISA COVID-19 product directly to hospitals and clinical labs, as well as sell it through distributors. The Company continues to sell its COVID-19 IgG/IgM Rapid Tests outside of the U.S.

For the fiscal years ended May 31, 2020 and 2019, the Company had three distributors and two distributors, respectively, which accounted for a total of 57.2% and 46.3% of our net consolidated sales, respectively. Of this, for the fiscal years ended May 31, 2020 and 2019, the largest of the distributors mentioned above accounted for 25.7% and 36.3%, respectively, of net consolidated sales.

At May 31, 2020 and 2019, the Company had three distributors and two distributors, respectively, which accounted for a total of 80.0% and 68.1%, respectively, of gross accounts receivable. Of the 80.0% as of May 31, 2020, 43.9% was owed by a distributor in Ecuador. Total gross receivables for fiscal 2020 and 2019 were \$1,836,852 and \$1,527,762, respectively.

#### **BACKLOG**

At May 31, 2020 and 2019, Biomerica had a backlog of unshipped orders of approximately \$727,000 and \$207,000 respectively. At May 31, 2020 this consisted primarily of orders to our distributor in Asia as well as some contract manufacturing work.

#### **RAW MATERIALS**

The principal raw materials utilized by Biomerica consist of various chemicals, serums, reagents and packaging supplies. Almost all of our raw materials are available from several sources, and we are not dependent upon any single source of supply or a few suppliers. However, due to the limited number of suppliers of some materials, especially those such as antibodies, there is always the possibility that the Company may encounter difficulty in the future obtaining key raw materials for its manufacturing processes or that such materials may be exceedingly costly. For the year ended May 31, 2020, one vendor accounted for 59.3% of our purchases of raw materials. For the year ended May 31, 2019, one vendor accounted for 23.8% of our purchases of raw materials.

Our inventory consists of various types of materials including antibodies, antigens, bottles, boxes, various chemicals and reagents utilized in the manufacture of our test kits as well as products in various stages of completion.

Our sourcing and receiving of raw materials have been negatively impacted due to the global COVID-19 pandemic. Many of our suppliers have been impacted by plant shut-downs, state or national mandates or recommended shut-downs, restrictions on distribution channels including ship freight, air freight and trucking, among other things. These suppliers are also experiencing their own disruptions in sourcing raw materials. It is unclear to what extent raw material availability will be impacted in the foreseeable future, and how that will impact our production and sales.

#### **COMPETITION**

Immunodiagnostic products, including COVID-19 products are currently produced globally by hundreds of companies. Biomerica is not a significant player in the overall market.

Our competitors vary greatly in size. Many are divisions or subsidiaries of well-established medical and pharmaceutical companies which are much larger than Biomerica and expend substantially greater amounts than we do for research and development, manufacturing, advertising and marketing.

The primary competitive factors affecting the sale of diagnostic products are uniqueness, technology, quality of product, performance, price, service and marketing. We believe we compete primarily on the basis of the uniqueness of our products, the quality of our products, the speed of our test results, our patent position, our pricing and our prompt shipment of orders. We offer a broad range of products, but have had limited marketing capability. We are working on expanding this capability through marketing and strategic cooperation with larger companies and distributors as well as hiring new marketing and sales expertise.

## **GOVERNMENT REGULATION OF OUR DIAGNOSTIC BUSINESS**

Our primary business consists of selling products that are generally legally defined to be in vitro diagnostic and medical devices. As a result, we are considered to be an in vitro diagnostic and medical device manufacturer, and as such are subject to the regulations of numerous governmental entities. These agencies include the FDA, Environmental Protection Agency, Federal Trade Commission, Occupational Safety and Health Administration, U.S. Department of Agriculture ("USDA"), and Consumer Product Safety Commission. These activities are also regulated by various agencies of the states and localities in which our products are sold. These regulations govern the introduction of new medical devices, the observance of certain standards with respect to the manufacture and labeling of medical devices, the maintenance of certain records, the reporting of potential product problems, and other matters.

The Food, Drug & Cosmetic Act of 1938 (the "FDCA") regulates medical devices in the United States by classifying them into one of three classes based on the extent of regulation believed necessary to ensure safety and effectiveness. Class I devices are those devices for which safety and effectiveness can reasonably be assured through general controls, such as device listing, adequate labeling, and adherence to the Quality System Regulation ("QSR") as well as Medical Device Reporting ("MDR"), labeling and other regulatory requirements. Some Class I medical devices are exempt from the requirement of Pre-Market Notification or clearance. Class II devices are those devices for which safety and effectiveness can reasonably be ensured through the use of special controls, such as performance standards, post-market surveillance and patient registries, as well as adherence to the general controls provisions applicable to Class I devices. Class III devices are devices that generally must receive clearance prior to marketing by the FDA pursuant to a pre-market approval to ensure their safety and effectiveness. Generally, Class III devices are limited to life-sustaining, life-supporting or implantable devices. However, this classification can also apply to novel technology or new intended uses or applications for existing devices. The Company's products are primarily either Class I or Class II medical devices.

Pursuant to FDA requirements, we have registered our manufacturing facility with the FDA as a medical device manufacturer, and listed the medical devices we manufacture. We are also subject to inspection on a routine basis for compliance with FDA regulations. This includes the QSR, which requires that we manufacture our products and maintain our documents in a prescribed manner with respect to issues such as design controls, manufacturing, testing and validation activities. Further, we are required to comply with other FDA requirements with respect to labeling and MDR regulation which requires that we provide information to the FDA on deaths or serious injuries alleged to have been associated with the use of our products, as well as product malfunctions that are likely to cause or contribute to death or serious injury if the malfunction were to recur. We believe that we are currently in material compliance with all relevant QSR and MDR requirements.

In addition, our facility is required to have a California Medical Device Manufacturing License. The license is not transferable and must be renewed biannually. Approval of the license requires that we be in compliance with QSR, labeling and MDR regulations. Our current license expires on December 31, 2020. These licenses are renewed periodically, and to date we have never failed to obtain a renewal.

Through compliance with FDA and California regulations, we can market some of our medical devices throughout the United States. International sales of medical devices are also subject to the regulatory requirements of each country. In Europe, the directives of the European Union ("EU") require that a device have a CE Mark in order to be sold in EU countries. The directive went into effect beginning December 7, 2003. The Company has completed the process for complying with the CE Mark directives; and In Vitro Diagnostics Directive 98/79/EC. We also comply with ISO 13485 for medical devices Quality Management Systems.

At present, outside the EU the regulatory international review process varies from country to country. We, in general, rely upon our distributors and sales representatives in the foreign countries in which we market our products to ensure that we comply with the regulatory laws of those countries. We believe that our international sales to date have been in compliance with the laws of all foreign countries in which we have made sales. Exports of most medical devices are also subject to certain FDA regulatory controls.

The designing, development, manufacturing, marketing, post-market surveillance, distribution, advertising and labeling of Biomerica's immunoassay in vitro diagnostic ("IVD") medical device products are subject to regulation in the United States by the Center for Devices and Radiological Health of the FDA and state agencies. FDA regulations require that some new products have pre-marketing clearance or approval by the FDA and require certain products to be manufactured in accordance with the FDA's "Good Manufacturing Practice" regulations, to be extensively tested and to be properly labeled to disclose test results and performance claims and limitations. After a product that is subject to FDA regulation is placed on the market, numerous regulatory requirements apply, including, for example, the requirement that we comply with recordkeeping and reporting requirements, such as the FDA's medical device reporting regulations and reporting of corrections and removals. The FDA enforces these requirements by inspection and market surveillance. The last FDA announced inspection was in November 2019 and no observations were noted. Biomerica is currently registered and licensed with the State of California's Department of Health Services. The Company believes that all Biomerica products sold in the U.S. comply with the FDA and state regulations.

Management believes that Biomerica's Quality Management System is in material compliance with the EN ISO 13485:2016. EN ISO 13485:2016 is an internationally recognized standard in which companies establish their methods of operation and commitment to quality.

We are an FDA regulated and ISO 13485:2016 certified In Vitro Diagnostic ("IVD") Medical Devices company. Our goal is to provide high quality medical diagnostic products that generally meet or exceed customer requirements and comply with all applicable regulatory requirements: FDA 21 CFR Part 820 Quality Management System, EN ISO 13485:2016, Medical Devices Quality Management Systems - Requirements for Regulatory Purposes, In Vitro Diagnostic Medical Devices Directive ("IVDD") 98/79/EC & and Medical Device Directive 93/42/EEC, Guidelines related to Medical Devices Directives and Guidance on CE Marking, etc. Biomerica involve its employees in a continuous improvement process to increase productivity, improve quality and maintain the suitability, adequacy, and effectiveness of our quality management system.

The new EU Medical Device Regulation ("MDR") 2017/745 entered into force on May 25, 2017. The MDR transition period ends May 26, 2021 and will replace Medical Device Directive ("MDD") 93/42/EEC. Manufacturers have less than one year to update their technical documentation and processes to meet the new, more stringent regulatory requirements of the European Union. Notified Bodies can begin certifying devices to the new MDR requirements once they have been designated under MDR by their Competent Authority. Our Notified Body recently became designated against MDR in July 2020.

The new EU In Vitro Diagnostic Medical Device Regulation ("IVDR") 2017/746 entered into force on May 25, 2017. The IVDR transition period ends May 26, 2022 and will replace IVDD 98/79/EC. Manufacturers have less than two years to update their technical documentation and processes to meet the new, more stringent regulatory requirements of the European Union. Notified Bodies can begin certifying devices to the new IVDR requirements once they have been designated under IVDR by their Competent Authority. The application process for Notified Bodies to be designated against IVDR takes 12-18 months. Our Notified Body is currently in the process of being designated under IVDR.

#### SEASONALITY OF BUSINESS

The businesses of the Company and its subsidiaries have not been subject to significant seasonal fluctuations.

#### INTERNATIONAL BUSINESS

The following table sets forth the dollar volume of revenue attributable to sales to domestic customers and foreign customers during the last two fiscal years for Biomerica:

Year Ended May 31	2020	2019
Europe	\$ 2,434,000/36.4%	\$ 1,694,000/32.6%
United States	445,000/6.6%	523,000/10.1%
Asia	1,867,000/27.9%	2,514,000/48.3%
S. America	1,615,000/24.1%	256,000/4.9%
Middle East	314,000/4.7%	214,000/4.1%
Other foreign	18,000/ 0.3%	--%
Total Sales	\$ 6,693,000/100%	\$ 5,201,000/100%

We recognize that our foreign sales could be subject to some special or unusual risks, which are not present in the ordinary course of business in the United States. Changes in economic factors, government regulations, terrorism, tariffs and import restrictions, disruptions in shipping and distribution channels and drop in demand for our products due to regional or national shut-downs from the COVID-19 pandemic, patients' fear or refusal to visit hospitals and healthcare providers due to the pandemic where our products are sold and used, the erosion of economic conditions in those countries, and many other factors all could impact sales within certain foreign countries. In addition, these factors could also impact the ability of the Company to collect foreign accounts receivable. Foreign countries have licensing requirements applicable to the sale of diagnostic products, which vary substantially from domestic requirements; depending upon the product and the foreign country, these may be more or less restrictive than requirements within the United States and may change without notice. Foreign diagnostic sales at Biomerica are made primarily through a network of approximately 100 independent distributors in approximately 65 countries.

The COVID-19 related factors mentioned above have also negatively impacted domestic sales of our non-Covid-19 products and may continue to negatively impact our domestic and international sales into the foreseeable future.

## **INTELLECTUAL PROPERTY**

We regard the protection of our methodologies, designs, product formulations, manufacturing processes, diagnostic procedures, copyrights, service marks, trademarks and trade secrets as important to our future success. We rely on a combination of copyright, trademark, patent, service mark and trade secret laws and contractual restrictions to establish and protect our proprietary rights in products and services. We have entered into confidentiality and invention assignment agreements with our employees and contractors, and nondisclosure agreements with most of our fulfillment partners and strategic partners to limit access to and disclosure of proprietary information. We cannot be certain that these contractual arrangements or the other steps taken by us to protect our intellectual property will prevent misappropriation of our technology. We have licensed in the past, and expect that we may license in the future, certain of our proprietary rights, such as trademarks, patents or copyrighted material, to third parties. While we attempt to ensure that the quality of our product brands is maintained by such licensees, we cannot be certain that such licensees will not take actions that might hurt the value of our proprietary rights or reputation.

## **LICENSE OF THIRD-PARTY INTELLECTUAL PROPERTY**

On occasion, we in-licensed both exclusive and non-exclusive rights to intellectual property and patents owned by third parties. These license agreements typically require royalties and other payments.

The Company has a royalty agreement in which it has obtained rights to manufacture and market an ACTH test (used to detect chronic metabolic conditions). Royalty expense of approximately \$15,000 and \$19,000, respectively, is included in cost of sales for this agreement for the fiscal years ended May 31, 2020 and 2019. Sales of products manufactured under this agreement are non-material to total sales for the fiscal years ended May 31, 2020 and 2019, respectively. The Company may license other products or technology in the future as it deems necessary or opportunistic for conducting business.

In April 2020, we signed two license agreements with the Icahn School of Medicine at Mount Sinai, a New York not-for-profit education corporation, pertaining to certain technology that we have used to develop our ELISA COVID-19 serology test. This agreement requires a royalty payment on all sales of products that utilize the licensed technology.

In May, 2020, we signed an exclusive license agreement with The Regents of the University of California, to license patents pertaining to a CRISPR-based technology that we hope to use to produce a rapid test for the COVID-19 virus, that could be used to test individuals to determine if they are currently infected with the COVID-19 virus. This agreement requires the payment of certain milestone payments and a royalty on all sales that utilize the licensed technology.

Some of the products that we manufacture, sell or use may be covered by claims in issued patents held by other persons or entities, and as such, upon notice from such persons or entity we may be required to pay a license fee or may be required to cease all manufacture, sale or use of such products, which could negatively impact the Company. While we have not been notified of any such claims by third parties, we cannot guarantee that such claims will not be made in the future.

## BRANDS AND TRADEMARKS

We occasionally register our tradenames with the Office of Patents and Trademarks. Of note, we registered the tradename "InFoods" on December 24, 2016. Our unregistered tradenames are "EZ Detect", "EZ-H.P." and "EZ-PSA". A trademark for "Aware" was issued and assigned in November 2001 and renewed in 2011. On January 11, 2020, the USPTO renewed the Company's "FORTEL" trademark for another ten years.

The laws of some foreign countries do not protect our proprietary rights to the same extent as do the laws of the U.S. Effective copyright, trademark and trade secret protection may not be available in such jurisdictions.

## PATENTS AND INFOODS TECHNOLOGY

The Company has filed over 100 international and PCT patents, and has 22 provisional and non-provisional patents currently filed with the USPTO. Some of these patent applications pertain to COVID-19 and other products. However, the majority of our patents that are pending pertain to the InFoods® IBS technology platform.

Our most important family of patent applications pertains to our InFoods® IBS technology platform, which is a revolutionary and disruptive new method of the symptoms of many different diseases. Our first planned product launch using this technology is the InFoods® IBS product which diagnoses and treats Irritable Bowel Syndrome. Using a patient blood sample, a physician or lab can run our test to identify specific foods (e.g. pork, milk, shrimp, broccoli, eggs) that, if eliminated from the patient's diet, can alleviate or reduce the individual's IBS symptoms, including, but not limited to, constipation, diarrhea, bloating, severe pain and indigestion. We have filed many patent applications with the USPTO and with other such similar agencies in other countries outside of the United States pertaining to this InFoods® IBS technology. These patent applications include claims that address the diagnosis and treatment of several disease states including IBS, functional dyspepsia, Crohn's disease, ulcerative colitis, gastroesophageal reflux disease, migraine headaches, osteoarthritis, psoriasis and others. These applications include the use of this technology in both humans and animals. The first patents filed by us pertained to IBS. The International Search Authority ("ISA") has deemed that for one of Biomerica's key patent applications pertaining to IBS, all of the International Patent Application claims for its composition and methods to identify trigger foods for IBS are novel and non-obvious. Several of the patents pertaining to the InFoods® IBS technology have been issued and many more are in active review and prosecution.

In August 2018, the Korean Intellectual Property Office ("KIPO") issued a Certificate of Patent (#10-1887545) covering our InFoods® IBS product (entitled "COMPOSITIONS, DEVICES, AND METHODS OF IBS SENSIVITY TESTING"). This patent was the first for the InFoods® patent portfolio, providing patent protection for InFoods® IBS in Korea until November 13, 2035.

In June 2019, we received our first issued patent from the USPTO (#15/526,240) pertaining to our InFoods® IBS product, with claims that covers the test kit that is used to determine patient food intolerances.

In May 2020, the Japanese Patent Office issued our first InFoods® IBS patent in that country (JP,6681907,B) which covers the compositions, devices and methods of IBS sensitivity testing.

In August 2020, we received notice of allowance from the USPTO for our second patent for the InFoods® IBS product (#16/385,322) that expands our claims to include the method for identifying and setting the antibody cut-off values for each individual food to determine if a person has an intolerance to that food.

We believe the claims in these issued InFoods IBS patents, and claims in pending patents that protect the use of the InFoods® IBS technology to diagnose and treat other diseases, provide us with broad protections from other companies making or selling competing products in this highly disruptive new field of medicine.

In addition to the use of our own patents, Biomerica has acquired from third parties the rights to manufacture and sell certain products that are protected by patents or intellectual property owned by these third parties. In some cases, royalties are paid on the sales of these products. Biomerica anticipates that it will license or purchase the rights to other products or technologies in the future.

## EMPLOYEES

As of May 31, 2020 and 2019, the Company employed 45 and 39 employees, respectively, in the U.S. and Europe. Various employees listed in the production department also perform research and development duties as a routine function of their job. The Company occasionally employs temporary employees when needed. The following is a breakdown of employees by departments:

	2020	2019
Administrative	5	4
Research and Development	9	8
Marketing & Sales	3	4
Production and Operations	28	23
Total	45	39

In addition, Biomerica de Mexico employs 20 people at its Mexico facility.

We also engage the services of many outside Ph.D. and M.D. and other types of industry expert consultants as well as medical institutions for technical support, regulatory advisors, marketing and public relations advisors, financial advisors, contract product development and manufacturing organization, and other advisors on a regular basis. We try to protect the Company with the use of confidentiality, intellectual property ownership and indemnifications agreements. However, we cannot guarantee that the use of such third parties will fully protect the Company from third-party claims or from theft of our intellectual property.

### ITEM 1A. RISK FACTORS

The risks described below are not the only ones we face. Additional risks and uncertainties we are not presently aware of or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks and uncertainties. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained or incorporated by reference into this annual report on Form 10-K, including our consolidated financial statements and related notes.

#### RISKS RELATED TO OUR BUSINESS

##### **Our business could be adversely affected by the effects of widespread public health epidemics.**

We are susceptible to a widespread outbreak of an illness or other health issue, such as the recent COVID-19 Coronavirus outbreak first reported in Wuhan, Hubei Province, China in December 2019 and subsequently spreading throughout the world resulting in millions of confirmed cases worldwide and many deaths. The outbreak of the COVID-19 virus has caused the various governments, including the U.S., to implement quarantines, various restrictions on travel causing airlines to suspend international and certain domestic flights, shelter in place orders and other restrictions. Governments have also implemented work restrictions that prohibit many employees from going to work, and for businesses that are allowed to remain open, many employees are electing to remain at home to avoid spread of the disease. As a result of this COVID-19 virus outbreak and potential future pandemic outbreaks, the Company faces significant risks including, but not limited to: a) supply chain disruptions making it difficult for the Company to contract and receive materials needed for production of its products, and needed to ship finished products to our end customers, b) loss of contracts and customers from the financial strains or other disruptions they are experiencing as a result of the pandemic, c) financial risks pertaining to receivables due from customers that may fall into insolvency or otherwise be unable to pay their bills, d) government responses including orders that make it difficult to remain open for business, restrict imports of raw materials or exports of finished goods, refusal to allow the Company's product to be licensed for sale in their countries, and other seen and unforeseen actions taken by government agencies, e) absenteeism or loss of employees at the Company, or at our partner's companies, due to health reasons or government restrictions, that are needed to develop, validate, manufacture and perform other necessary functions for our operations, f) equipment failures, loss of utilities and other disruptions that could impact our operations or render them inoperable, g) litigation or government actions against the Company pertaining to existing products new products sold by the Company that are directed at limiting or treating the spread of the pandemic outbreak, h) a local or global recession or depression that could harm the international banking system, limit demand for all products including those made by the Company, i) a drop in demand for our products, that are all medical related, due to patients' reluctance or refusal to visit hospitals, labs, and doctors' offices where our products are used due to their fear of contracting a disease, and many other seen and unforeseen events and circumstances, all of which could negatively impact the Company.

**If our COVID-19 tests are unable to gain acceptance in the market, proves to be ineffective or less effective than expected, and/or we do not receive regulatory approvals for our COVID-19 tests to be sold, our results of operation could be materially harmed.**

Although we believe that our COVID-19 tests represent promising tests to detect prior COVID-19 virus exposure, the tests may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for our COVID-19 antibody tests. Gaining acceptance in medical communities requires increasing awareness of our COVID-19 tests and their benefits. Also, there are a large number of companies around the world now making and selling COVID-19 tests that compete with our COVID-19 tests. Many of these competitor products are made in China and other parts of Asia where manufacturing costs are low. As such, we are seeing supply and price competition which could make it difficult for the Company to compete. Other risks pertaining to these products include:

- our ability to demonstrate the efficacy, speed and cost competitiveness of our COVID-19 tests;
- whether healthcare providers and governmental agencies believe our COVID-19 tests are sufficiently safe, effective, and accurate;
- our ability to transfer, further develop, integrate and use third-party licensed technology;
- our ability to manufacture and scale commercial products;
- our ability to source required raw materials in a cost effective and timely manner;
- development of effective vaccines to the Covid-19 virus that reduce the need to do antibody testing;
- mutations in the COVID-19 virus that render our tests ineffective;
- receipt of regulatory approvals necessary prior to commercialization of our products;
- the FDA or other regulatory agencies retracting their prior approval for our products to be sold in their market or changing regulations for approval; and
- whether the medical community accepts our COVID-19 tests as a supplement to, alternative to, or complimentary to, current PCR or other tests for COVID-19 infection.

In addition, each country in which we wish to sell these tests has its own regulatory approval requirements. We will need to comply with the regulatory requirements of each country before we are permitted to sell in that country. There can be no assurance that governmental agencies, including the FDA, will provide clearance of our COVID-19 tests to be sold in their markets. Failure to achieve widespread market acceptance of our COVID-19 tests, or failure to achieve regulatory clearance of our COVID-19 tests, could materially harm our business, financial condition, and results of operations. Our COVID-19 tests are new tests that only generated revenue during the last two months of our fiscal year. It is uncertain how long we will be able to generate revenues from these tests, and what level of sales, if any, we will attain in the future.

**Our operating results may fluctuate adversely as a result of many factors that are outside our control, which may negatively impact our stock price. Fluctuations in our operating results, for any reason, could cause our growth or operating results to fall below the expectations of investors and securities analysts.**

We base the scope of our operations and related expenses on our estimates of future revenues. A significant portion of our operating expenses are fixed, and we may not be able to rapidly adjust our expenses if our revenues fall short of our expectations. Our revenue estimates for future periods are based, among other factors, on estimated end-user demand for our products. If end-user consumption is less than estimated, revenues from our distribution partners and other distribution channels would be expected to fall short of expectations, and because such a significant portion of our costs are fixed, could result in operating losses.

Factors that are beyond our control and that could affect our operating results in the future include:

- regulatory clearance;
- changes in the level of competition, such as would occur if one of our competitors introduced a new, better performing or lower priced product to compete with one or more of our products;
- changes in the reimbursement systems or reimbursement amounts that end-users may rely upon in choosing to use our products;

- changes in economic conditions in our domestic and international markets, such as economic downturns, decreased healthcare spending, reduced consumer demand, inflation and currency fluctuations; changes in government laws and regulations affecting our business; reluctance for consumers to visit healthcare providers;
- lower than anticipated market penetration of our new or more recently introduced products;
- significant quantities of our product or that of our competitors in our distributors' inventories or distribution channels;
- changes in distributor buying patterns;
- government mandated shelter-in-place or other lock-down orders;
- continued spread of the COVID-19 virus or mutations of the virus; and
- changes in the healthcare market including consolidation in our customer base.

**To remain competitive, we must continue to develop, obtain and protect our proprietary technology rights; otherwise, we may lose market share or need to reduce prices as a result of competitors selling technologically superior products that compete with our products.**

Our ability to compete successfully in the diagnostic market depends on continued development and introduction of new products, technology and the improvement of existing technology. If we cannot continue to improve upon or develop, obtain and protect our technology, our operating results could be adversely affected.

Our competitive position is heavily dependent on obtaining and protecting our own proprietary technology or obtaining licenses from others. Our ability to obtain patents and licenses, and their benefits, is uncertain.

**The Company is required to obtain government or regulatory certification in many countries and the European community to sell its products in those countries or regions. There is no assurance that the Company will be able to retain its certification in the future.**

Significant government regulation exists in countries in which we conduct business. A large part of the Company's sales are to distributors in Europe, China and other countries, which require us to maintain certain certifications to sell our products. Failure to comply with current governmental regulations and quality assurance guidelines could cause the loss of these certifications, which could materially adversely affect the results of the Company. Loss of certifications could lead to temporary manufacturing shutdowns, product recalls, product shortages or delays in product manufacturing and a decline in sales.

**The Company maintains a manufacturing plant in Mexico which presents risks to the Company including risks associated with doing business outside the United States.**

The Company has a significant investment in its manufacturing facility in Mexico through its subsidiary, Biomerica de Mexico. There are a number of risks associated with doing business in Mexico, including, exposure to local economic and political conditions, social unrest, including risks of terrorism or other hostilities, export and import restrictions, the potential for shortages of trained labor, and the possible effects of currency exchange rate fluctuations. These risks could lead to additional costs that we cannot foresee at this time and may materially adversely impact our business, results of operations and financial condition.

**We use hazardous materials in our research and production that may result in unexpected and substantial claims against us relating to handling, storage or disposal.**

We use hazardous materials in our research and production. The risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any harm or damages that result and any such liability could exceed the resources of the Company. The Company may incur substantial costs to comply with environmental regulations.

If any governmental authorities were to impose new environmental regulations requiring compliance in addition to that required by existing regulations, or alter their interpretation of the requirements of such existing regulations, such environmental and safety regulations could impair our research, development or production efforts by imposing additional, and possibly substantial, costs, restrictions or compliance procedures on our business. In addition, because of the nature of the penalties provided for in some of these environmental and safety regulations, we could be required to pay sizable fines, penalties or damages in the event of noncompliance with regulations and environmental laws. Any environmental or safety violation or remediation requirement could also partially or completely shut down our research and manufacturing facilities and operations, which would have a material adverse effect on our business. The risk of accidental contamination or injury from these hazardous materials cannot be completely eliminated and exposure of individuals to these materials could result in substantial fines, penalties or damages that may not be covered by insurance.

**In order to remain competitive, we must expend considerable resources to research new technologies and products and develop new markets, and there is no assurance our efforts to develop new technologies, products or markets will be successful or such technologies, products or markets will be commercially viable.**

We devote a significant amount of financial and other resources to researching and developing new technologies, new products and new markets. The development, manufacture and sale of diagnostic products require a significant investment of resources. The development of new products and markets also requires a substantial investment of resources, such as new employees, offices and manufacturing facilities, consultants and clinical trials. No assurances can be given that our efforts to develop new technologies or products will be successful, that such technologies and products will be commercially viable, or our expansion into new markets will be profitable.

There is also no guarantee that our new products, including our InFoods® IBS products, will get approval and be well accepted into the marketplace.

Our operations will be adversely affected if our operating results do not correspondingly increase with our increased expenditures or if our technology, product and market development efforts are unsuccessful or delayed. Furthermore, our failure to successfully introduce new technologies or products and develop new markets could have a material adverse effect on our business and prospects.

**We rely on a limited number of key distributors that account for a substantial majority of our total revenue. The loss of any key distributor or an unsuccessful effort by us to directly distribute our products could lead to reduced sales.**

For the fiscal years ended May 31, 2020 and 2019, the Company had three and two distributors, respectively, which accounted for a total of 57.2% and 46.3% of our sales, respectively. Of this, for the fiscal years ended May 31, 2020 and 2019, one of the distributors mentioned above accounted for 25.7% and 36.3%, respectively, of net consolidated sales.

At May 31, 2020 and 2019, the Company had three distributors and two distributors which accounted for a total of 80.08% and 68.1%, respectively, of gross accounts receivable. The loss of these sales to these accounts could adversely impact the results of the Company. Of the 80.0% as of May 31, 2020, 43.9% was owed by a distributor in Ecuador. Total gross receivables for fiscal 2020 and 2019 were \$1,836,852 and \$1,527,762, respectively. Adverse changes in our relationships with these distributors and other partners, or adverse developments in their financial condition, performance or purchasing patterns, could adversely affect our business and consolidated financial statements.

**We extend credit to customers outside the U.S. which can be difficult to collect.**

We extend credit to many of our customers including those outside of the U.S. It is often difficult to obtain adequate credit information on these customers. Further, our ability to collect receivables from these customers through the court systems in those countries can be more difficult than here in the U.S. Our inability to collect on receivables from customers outside of the U.S. could negatively impact the Company.

**If we are not able to manage our growth strategy our operating results may be adversely affected.**

Our business strategy contemplates further growth, which would likely result in expanding the scope of operating and financial systems and the geographical area of our operations, including further expansion outside the U.S., as new products and technologies are developed and commercialized or new geographical markets are entered. Because we have a small executive staff, acquisitions and other future growth may divert management's attention from other aspects of our business, and place a strain on existing management and our operational, financial and management information systems. Furthermore, we may expand into markets in which we have less experience or incur higher costs.

**Intellectual property risks and third-party claims of infringement, misappropriation of proprietary rights or other claims against us could adversely affect our ability to market our products, require us to redesign our products or attempt to seek licenses from third parties, and materially adversely affect our operating results. In addition, the defense of such claims could result in significant costs and divert the attention of our management and other key employees.**

Companies in or related to our industry often aggressively protect and pursue their intellectual property rights. There are often intellectual property risks associated with developing and producing new products and entering new markets, and we may not be able to obtain, at reasonable cost or upon commercially reasonable terms, if at all, licenses to intellectual property of others that is alleged to be part of such new or existing products.

We have hired and will continue to hire individuals or contractors who have experience in medical diagnostics and these individuals or contractors may have confidential trade secret or proprietary information of third parties. We cannot assure you that these individuals or contractors will not use this third-party information in connection with performing services for us or otherwise reveal this third-party information to us. Thus, we could be sued for misappropriation of proprietary information and trade secrets. Such claims are expensive to defend and could divert our attention and result in substantial damage awards and injunctions that could have a material adverse effect on our business, financial condition or results of operations. In addition, to the extent that individuals or contractors apply technical or scientific information independently developed by them to our projects, disputes may arise as to the proprietary rights to such data and may result in litigation.

The defense and prosecution of patent and trade secret claims are both costly and time consuming. We or our customers may be sued by other parties that claim that our products have infringed their patents or misappropriated their proprietary rights or that may seek to invalidate one or more of our patents. An adverse determination in any of these types of disputes could prevent us from manufacturing or selling some of our products, limit or restrict the type of work that employees involved with such products may perform for us, increase our costs and expose us to significant liability.

**As a general matter, our involvement in litigation or in any claims to determine proprietary rights, as may arise from time to time, could materially and adversely affect our business, financial condition and results of operations for reasons such as:**

- pending litigation may of itself cause our distributors or end-users to reduce or terminate purchases of our products;
- it may consume a substantial portion of our managerial and financial resources;
- its outcome would be uncertain and a court may find any third-party patent claims valid and infringed by our products (issuing a preliminary or permanent injunction) that would require us to procure costly licensing arrangements from third parties or withdraw or recall such products from the market, redesign such products offered for sale or under development or restrict employees from performing work in their areas of expertise;
- governmental agencies may commence investigations or criminal proceedings against our employees, former employees and us relating to claims of misappropriation or misuse of another party's proprietary rights;
- an adverse outcome could subject us to significant liability in the form of past royalty payments, penalties, special and punitive damages, the opposing party's attorneys' fees, and future royalty payments significantly affecting our future earnings; and
- failure to obtain a necessary license (upon commercially reasonable terms, if at all) upon an adverse outcome could prevent us from selling our current products or other products we may develop.

In addition to the foregoing, we may also be required to indemnify some customers, distributors and strategic partners under our agreements with such parties if a third party alleges or if a court finds that our products or activities have infringed upon, misappropriated or misused another person's proprietary rights. Further, our products may contain technology provided to us by other parties such as contractors, suppliers or customers. We may have little or no ability to determine in advance whether such technology infringes the intellectual property rights of a third party. Our contractors, suppliers and licensors may not be required or financially able to indemnify us in the event that a claim of infringement is asserted against us, or they may be required to indemnify us only up to a maximum amount, above which we would be responsible for any further costs or damages.

Some of the products that we manufacture, sell or use may be covered by claims in issued patents held by other persons or entities, and as such, upon notice from such persons or entity, we may be required to pay a license fee or may be required to cease all manufacture, sale or use of such products, which could negatively impact our financial results or operations. We cannot guarantee that such claims will not be made in the future.

**We need to continue to raise additional funds to finance our future capital or operating needs, which could have adverse consequences on our operations and the interests of our stockholders.**

We need to continue to raise funds through public or private debt or sale of equity to achieve our business strategy. When we raise funds or acquire other technologies or businesses through issuance of equity, this dilutes the interests of our stockholders. Moreover, the availability of additional capital, whether debt or equity from private capital sources (including banks) or the public capital markets, fluctuates as our financial condition and industry or market conditions in general change. There may be times when the private capital markets and the public debt or equity markets lack sufficient liquidity or when our securities cannot be sold at attractive prices, in which case we would not be able to access capital from these sources on favorable terms, if at all. We can give no assurance as to the terms or availability of additional capital.

Our inability to raise additional funds to finance our future capital or operating needs could force us to delay, reduce or eliminate our development programs or commercialization efforts.

Costs related to development projects and approvals are hard to estimate due to factors that are unknown to us at this time. These costs could be much higher than anticipated and current operations may not be able to cover these costs.

**Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of studies and trials may not be predictive of future trial results.**

Clinical trials are expensive, time consuming and difficult to design and implement. Regulatory agencies may analyze or interpret the results differently than we do. Even if the results of our clinical trials are favorable, the clinical trials for a number of our product candidates may take a significant amount of time to complete. Regulatory authorities, including state and local authorities, may suspend, delay or terminate our clinical trials at any time, require us to conduct additional clinical trials, require a particular clinical trial to continue for a longer duration than originally planned, or require a change to our development plans such that we conduct clinical trials for a product candidate in a different order. There is no assurance that the results of the clinical trials will be positive. A negative clinical trial could affect our ability to obtain regulatory clearances and/or potential licensing partners. There is also no assurance that our clinical trials will not be delayed or will be completed. Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

**Our results of operations and financial conditions may be adversely affected by the financial soundness of our customers, distributors and suppliers.**

If our customers' or suppliers' operating and financial performance deteriorates, or if they are unable to make scheduled payments or obtain credit, our customers may not be able to pay, or may delay payment of, accounts receivable owed to us, and our suppliers may restrict credit or impose different payment terms or reduce or terminate production of products they supply to us, or may cease all operations. Any inability of customers to pay us for our products and services, or any demands by suppliers for different payment terms, or inability for such suppliers to continue operations may adversely affect our operating results and financial condition. Additionally, both state and federal government sponsored and private payers, as a result of budget deficits or reductions, may seek to reduce their healthcare expenditures by cutting or eliminating reimbursements for, or cutting purchase of our products. Any reduction in payments by such government sponsored or private payers may adversely affect our earnings and cash flow.

**We may not achieve market acceptance of our new products among healthcare providers and physicians, and this would have a negative effect on future sales.**

We believe our ability to introduce new products that gain acceptance among healthcare providers and physicians is an important part of our ability to grow our revenue in future periods. However, any new products we introduce may not gain market acceptance to the extent we anticipate or project. The acceptance of which in the medical community is unpredictable at this time. In addition, the Company will need to spend considerable funds in order to introduce the products into the marketplace. Sales, if any, of these products in the future are uncertain. In addition, our competitors may offer different products and product formats at suggested prices that are lower than for our products or are more accurate than our products. We can provide no assurances that the medical community will purchase our products or that they will not prefer to purchase a competitive product.

**The industry and market segments in which we operate are highly competitive, and intense competition with other providers of diagnostic products may reduce our sales and margins.**

Our diagnostic tests compete with similar products made by our competitors. There are a large number of multinational and regional competitors making investments in competing technologies and products. We also face competition from our distributors as some have created, and others may decide to create, their own products to compete with ours. A number of our competitors have a potential competitive advantage because they have substantially greater financial, technical, research and other resources, and larger, more established marketing, sales, distribution and service organizations than we have. Moreover, some competitors offer broader product lines and have greater name recognition than we have. If our competitors' products are more effective than ours or take market share from our products through more effective marketing or competitive pricing, our operating results could be materially and adversely affected.

In addition, there has been a trend toward industry consolidation in our markets over the last few years. We may not be able to compete successfully in an increasingly consolidated industry. We expect this trend toward industry consolidation may continue as companies attempt to strengthen or hold their market positions in an evolving industry and as companies are acquired or are unable to continue operations.

**Our business and products are highly regulated by various governmental agencies. Our results of operations would be negatively affected by failures or delays in the receipt of regulatory approvals or clearances, the loss of previously received approvals or other changes to the existing laws and regulations that adversely impact our ability to manufacture and market our products.**

The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities in the U.S., principally the FDA and corresponding state and foreign regulatory agencies. Our future performance depends on, among other matters, if, when and at what cost we will receive regulatory approval for new products, and if we can continue to comply with the many regulatory requirements that enable us to manufacture and sell medical related products and tests. Regulatory review can be a lengthy, expensive and uncertain process, making the timing and costs of clearances and approvals difficult to predict. Meeting all regulatory requirements, laws and mandates, and maintaining compliance with such in order to manufacture and sell medical products can be difficult and expensive. Our results of operations would be negatively affected by failures or delays in the receipt of regulatory approvals or clearances, the loss of previously received approvals or clearances, the placement of limits on the marketing and use of our products, and restrictions on our ability to manufacture our products.

**Changes in government policy could adversely affect our business and potential profitability.**

Changes in government policy could have a significant impact on our business by increasing the cost of doing business, affecting our ability to sell our products and negatively impacting our profitability. Such changes could include tariffs or modifications to existing legislation, such as U.S. tax policy, or entirely new legislation, such as the Affordable Healthcare Act ("AHA") in the U.S. We cannot fully predict the many ways that healthcare reform might affect our business. It is unclear whether and to what extent, if at all, other anticipated developments, including changes due to new presidential administration priorities, or changes resulting from healthcare reform, such as a change in the number of people with health insurance, may impact us.

**We are subject to numerous government regulations in addition to FDA regulation, and compliance with laws, including changed or new laws, could increase our costs and adversely affect our operations. There is also the risk that our facilities could fail to get the proper licensing at our next inspection or renewal.**

In addition to FDA and other regulations referred to above, numerous laws relating to such matters as safe working conditions, manufacturing practices, data privacy, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances impact our business operations. If these laws or their interpretation change or new laws regulating any of our businesses are adopted, the costs of compliance with these laws could substantially increase our overall costs. Failure to comply with any laws, including laws regulating the manufacture and marketing of our products, could result in substantial costs and loss of sales or customers. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of future legislation or regulatory developments relating to our industry and our products. To the extent the costs and procedures associated with meeting new or changing requirements are substantial, our business, results of operations and financial condition could be adversely affected.

**Our total revenue could be affected by third-party reimbursement policies and potential cost constraints.**

The end-users of our products are primarily physicians, labs and other healthcare providers. In the U.S., healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third-party payers, principally private health insurance plans, federal Medicare and state Medicaid, to reimburse all or part of the cost of the procedure. Use of our products would be adversely impacted if physicians and other healthcare providers do not receive adequate reimbursement for the cost of our products by their patients' third-party payers both in the U.S. and in foreign markets. Our total revenue could also be adversely affected by changes or trends in reimbursement policies of governmental or private healthcare payers. We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in recent years, currently available levels of reimbursement may not continue to be available in the future for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the U.S. or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, regulation or reimbursement policies of third-party payers may reduce the demand for our products or adversely impact our ability to sell our products on a profitable basis.

**Unexpected increases in, or inability to meet, demand for our products could require us to spend considerable resources to meet the demand or harm our reputation and customer relationships if we are unable to meet demand.**

Our inability to meet customer demand for our products, whether as a result of manufacturing problems or supply shortfalls, could harm our customer relationships and impair our reputation within the industry. In addition, our product manufacturing of certain product lines is concentrated in our two manufacturing sites. Weather, natural disasters (including pandemics), fires, terrorism, political change, failure to follow specific internal protocols and procedures, equipment malfunction, environmental factors or damage to one or more of our facilities could adversely affect our ability to manufacture our products. This, in turn, could have a material adverse effect on our business.

If we experience unexpected increases in the demand for our products, we may be required to expend additional capital resources to meet these demands. These capital resources could involve the cost of new machinery or even the cost of new manufacturing facilities. This would increase our capital costs, which could adversely affect our earnings and cash resources. If we are unable to develop or obtain necessary manufacturing capabilities in a timely manner, our total revenue could be adversely affected. Failure to cost-effectively increase production volumes, if required, or lower than anticipated yields or production problems, including those encountered as a result of changes that we may make in our manufacturing processes to meet increased demand or changes in applicable laws and regulations, could result in shipment delays as well as increased manufacturing costs, which could also have a material adverse effect on our business, operating results and financial condition.

Unexpected increases in demand for our products could also require us to obtain additional raw materials in order to manufacture products to meet the demand. Some raw materials require significant ordering lead time and we may not be able to timely access sufficient raw materials in the event of an unexpected increase in demand, particularly those obtained from a sole supplier or a limited group of suppliers.

**If one or more of our products is claimed to be defective, or does not meet the performance criteria we claim in our marketing materials we could be subject to claims of liability and harm to our reputation that could adversely affect our business.**

A claim of 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 injuries and otherwise. Further, a claim that one of our products is defective or does not actually meet the performance criteria we claim in our marketing materials, could have a substantial impact on our revenues and financial performance. Any substantial underinsured loss resulting from such a claim would have a material adverse effect on our operating results and financial conditions and the damage to our reputation or product lines in the industry could have a material adverse effect on our business.

**We are exposed to business risks which, if not covered by insurance, could have an adverse effect on our results of operations. We face potential product liability exposure, and, if claims brought against us are successful, we could incur substantial liabilities.**

We face a number of business risks, including exposure to product liability claims, employment law claims, claims that the Company or its officers, directors or employees have engaged in illegal or wrongful acts, claims of violation of environmental laws and many other possible claims. Although we maintain insurance for a number of these risks, we may face claims for types of damages, or for amounts of damages, that are not covered by our insurance. For example, although we currently carry product liability insurance for liability losses, there is a risk that product liability or other claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy. Also, our existing insurance may not be renewed at the same cost and level of coverage as currently in effect, or may not be renewed at all. Further, we do not currently have insurance against many environmental risks we confront in our business. If we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, whether arising out of product liability matters, cybersecurity matters, or from some other matter, that claim could have a material adverse effect on our results of operations.

**We may rely on third parties to conduct or be part of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product candidates.**

We rely on third-party contract research organizations (“CROs”), Universities or/clinical sites (“Vendors”), to coordinate, monitor and conduct of our clinical trials and to manage data for our clinical programs. We, our Vendors, and our clinical sites are required to comply with current Good Clinical Practices (“GCPs”), regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our Vendors and at our clinical sites to confirm compliance with these requirements. In the future, if we, our Vendors or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. If our Vendors do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

**Failures in our information technology and storage systems could significantly disrupt our business or force us to expend excessive costs.**

We utilize complex information technology systems to support our business and store information. We cannot be sure that our systems will meet our future business needs or that necessary upgrades will operate as designed, which could result in excessive costs or disruptions in portions of our business. In particular, any disruptions, delays or deficiencies caused by our enterprise resource planning system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business. In addition, despite the implementation of security measures, information technology systems are vulnerable to damage from a variety of sources, including computer viruses, unauthorized access, telecommunications or network failures, malicious human acts, terrorism and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, could result in a material disruption in our operations. Furthermore, to the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could face a variety of negative consequences, including regulatory actions or litigation, fines or penalties, adverse publicity, increased cybersecurity protection costs, and lost revenue.

There is a risk that our measures to protect our systems from cyber-attack are not sufficient to avoid attacks by new sources and methods.

**Our business could be negatively affected by the loss of or the inability to hire key personnel.**

Our future success depends in part on our ability to retain our key technical, sales, marketing and executive personnel and our ability to identify and hire additional qualified personnel. Competition for these personnel is intense, both in the industry in which we operate and where our operations are located. Further, we expect to grow our operations, and our needs for additional management and other key personnel are expected to increase. If we are not able to retain existing key personnel, or timely identify and hire replacement or additional qualified personnel to meet expected growth, our business could be adversely impacted. In addition, the loss of any of our key personnel, particularly key research and development personnel, could harm our business and prospects and could impede the achievement of our research and development, operation or strategic objectives.

**We face risks relating to our international sales, including inherent economic, political and regulatory risks, which could impact our financial performance, cause interruptions in our current business operations and impede our growth strategy.**

Our products are primarily sold internationally, with the majority of our international sales to our distributors in Asia, Europe and South America. We currently sell and market our products through distributor organizations and sales agents which creates foreign risks include, among others:

- compliance with multiple different registration requirements and new and changing registration requirements, our inability to benefit from registration for our products inasmuch as registrations may be controlled by a distributor, and the difficulty in transitioning our product registrations;
- compliance with complex foreign and U.S. laws and regulations that apply to our international operations, including U.S. laws such as import/export limitations, the Foreign Corrupt Practices Act, and local laws;
- tariffs or other barriers as we continue to expand into new countries and geographic regions, especially related to China as tariffs are changing constantly;
- exposure to currency exchange fluctuations against the U.S. dollar;
- longer payment cycles, generally lower average selling prices and greater difficulty in accounts receivable collection;
- lack of ability to enforce receivables collections contracts in foreign legal courts;
- reduced, or lack of, protection for, and enforcement of, intellectual property rights;
- political and economic instability in some of the regions where we currently sell our products or that we may expand into in the future;
- complex and potentially adverse tax consequences; and
- diversion to the U.S. of our products sold into international markets at lower prices.

Currently, most of our international sales are negotiated for and paid in U.S. dollars. Nonetheless, these sales are subject to currency risks, since changes in the values of foreign currencies relative to the value of the U.S. dollar can render our products comparatively more expensive. These exchange rate fluctuations could negatively impact international sales of our products, as could changes in the general economic conditions in those markets. In order to maintain a competitive price for our products internationally, we may have to continue to provide discounts or otherwise effectively reduce our prices, resulting in a lower margin on products sold internationally. Continued change in the values of the Euro, the Mexican peso and other foreign currencies could have a negative impact on our business, financial condition and results of operations.

In addition, we have certain supply agreements with foreign vendors whereby we share the foreign currency exchange fluctuation risk. We may, in the future, enter into similar arrangements.

**Sales of our common stock in the public market could lower the market price for our common stock and adversely impact the trading price of our securities.**

Future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then prevailing market price of our common stock and could make it more difficult for us to raise funds in the future through a public offering of our securities.

On July 21, 2020, we filed with the SEC a new “Shelf” registration statement on Form S-3. The new registration statement registers our common shares to be issued in a maximum aggregate amount of \$90,000,000. Shares of our common stock may be sold from time to time under this registration statement once it is declared effective.

The issuance of additional shares of our common stock, or issuances of additional securities, could dilute the ownership interest of our common stockholders and could depress the market price of shares of our common stock and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock.

We also have a number of stockholders who own large blocks of our common stock. If one or more of these stockholders were to sell large portions of their holdings in a relatively short time, for liquidity or other reasons, the prevailing market price of shares of our common stock could be negatively affected.

**The price of our stock may fluctuate unpredictably in response to factors unrelated to our operating performance.**

The stock market periodically experiences significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price of our common stock to drop. In particular, the market price of our common stock has been very volatile and unpredictable and may vary substantially in the future in response to:

- announcements by us or our competitors concerning technological innovations;
- introductions of new products;
- FDA, SEC, FINRA and foreign regulatory actions against the Company;

- developments or disputes relating to patents or proprietary rights;
- failure to meet the expectations of stock market analysts and investors;
- changes in stock market analyst recommendations regarding our common stock;
- changes in healthcare policy in the U.S. or other countries;
- lawsuits or liability claims from shareholders or other parties; and
- general stock market conditions and other factors unrelated to our operating performance.

A sale of a substantial number of shares of the common stock by the Company may cause the price of our common stock to decline.

Trading of our common stock is not significant, therefore sales of a larger volume of the stock could adversely affect the stock price.

As of August 26, 2016, the Company's stock has been traded on the Nasdaq Capital Market. Trading of the Company's stock is limited and liquidation of the Company's stock may be difficult as there is a limited market for the Company's stock.

**Our ability to use our net operating loss carry forwards in the future may be subject to limitation.**

Although the Company has Federal income tax net operating loss carryforwards of approximately \$9,213,000 and California state income tax net operating loss carryforwards of approximately \$5,025,000, use of these loss carryforwards will depend on future income in relationship to expirations dates of these carryforwards.

**We do not anticipate declaring any cash dividends on our common stock.**

We have never declared or paid cash dividends on our common stock and do not plan to pay any cash dividends in the near future. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future. Further, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Consequently, in the foreseeable future, gains will likely only be experienced from investments in our common stock if the price of our common stock increases. There is no guarantee that our common stock will appreciate in value or even maintain the price at which shares were purchased, and returns may not be realized on investments in our common stock.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

The Company leases its office facilities. At May 31, 2020, the Company had approximately 22,000 square feet of floor space at its corporate headquarters at 17571 Von Karman Avenue in Irvine, California, 92614 which it has been leasing since 2009. The lease for its headquarters expired on August 31, 2016. The Company had an option to extend the term of its lease for two additional sixty-month periods. On November 30, 2015, the Company exercised its option to extend its lease for an additional sixty-month period and entered into the First Amendment to Lease wherein it extended its lease until August 31, 2021. The initial base rent for the lease extension was \$21,000 per month, increasing to \$23,637 through August 31, 2021. The rent is currently \$22,948 per month and will increase on September 1, 2020 to \$23,637 per month. The security deposit of \$22,080 remains the same. In November 2016, the Company's Mexican subsidiary, Biomerica de Mexico, entered into a 10-year lease for approximately 8,100 square feet of manufacturing space with initial base rent of \$2,926 per month. The Company has one 10-year option to renew at the end of the initial lease period. The rent is currently \$3,239 per month. Biomerica de Mexico also leases a smaller unit on a month-to-month basis for use in one manufacturing process. In addition, the Company leases a small office in Lindau, Germany on a month-to-month basis, as headquarters for BioEurope GmbH, its Germany subsidiary.

**ITEM 3. LEGAL PROCEEDINGS**

On July 2, 2020, we received a notice of investigation and subpoena to produce information and documents from the Division of Enforcement of the SEC. The subpoena seeks information and documents related to events and circumstances leading up to our March 17, 2020 announcement that we had commenced shipping samples of our COVID-19 IgG/IgM Rapid Test to countries outside of the United States, and had initiated the application process with the United States Food and Drug Administration under the COVID-19 Emergency Use Authorization for approval to market and sell the test in the United States. The subpoena also seeks information and documents about the identity of any persons who were aware of the substance of the March 17, 2020 announcement prior to that date, as well as certain corporate policies and documentation. We are cooperating and intend to continue cooperating fully with the SEC's investigation. At this time, we are unable to predict the duration, scope or outcome of this investigation.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II****ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

On August 2, 2016, the Company's common stock became listed and began trading on the Nasdaq Capital Market stock exchange where it trades under the symbol BMRA. Previous to that date, the Company's stock traded on the OTC Bulletin Board.

As of May 31, 2020, the number of holders of record of Biomerica's common stock was approximately 810, excluding stock held in street name. The number of record holders does not bear any relationship to the number of beneficial owners of the common stock as most of the Company's common stock is held in street name at securities brokerage firms.

The Company has not paid any cash dividends on its common stock in the past and does not plan to pay any cash dividends on its common stock in the foreseeable future. The Company's Board of Directors ("Board") intends, for the foreseeable future, to retain any earnings to finance the continued operation and expansion of the Company's business.

On June 30, 2017, the Company filed an S-3 Registration Statement with the SEC primarily for the purposes of raising capital to support its research, development and intellectual property projects. The registration statement became effective on July 20, 2017. A prospectus supplement to the Form S-3 Registration Statement was filed December 4, 2017 which stated that up to \$7,000,000 of funds would be raised from time to time under the Form S-3 Registration Statement through an At Market Issuance Sales Agreement ("ATM") with B. Riley, FBR, acting as the agent for these transactions. As of May 31, 2020, a total of approximately \$6,997,935 in gross proceeds had been raised under this prospectus supplement.

On March 20, 2020, the Company filed a second prospectus supplement to the base prospectus dated July 20, 2017 for purposes of raising up to \$12,500,000 from time to time pursuant to the terms of the ATM. As of May 31, 2020, a total of \$6,817,329 in gross proceeds had been raised under this prospectus supplement. No additional shares will be sold under this prospectus supplement.

On July 21, 2020, the Company filed with the SEC a new "Shelf" registration statement on Form S-3 to replace the registration statement that expired the day before. The new registration statement registers common shares to be issued in a maximum aggregate amount of \$90,000,000. Our shares of common stock may be sold from time to time under this registration statement once it is declared effective.

We did not purchase any of our shares of common stock or other securities during our fiscal year ended May 31, 2020.

The table below provides information relating to our equity compensation plans as of May 31, 2020:

Securities Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options	Compensation Plans Weighted-Average Exercise Price of Outstanding Options	Securities Remaining Available for Future Issuance Under Compensation Plans (Excluding those Reflected in First Column)
Equity compensation Plans approved by Securities holders	1,789,251	\$2.75	799,041

There were no sales of unregistered equity securities during the year ended May 31, 2020 except as described in Note 5-Shareholders' Equity- of the Consolidated Financial Statements.

## ITEM 6. SELECTED FINANCIAL DATA

Not required.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

EXCEPT FOR HISTORICAL INFORMATION CONTAINED HEREIN, THE STATEMENTS IN THIS ANNUAL REPORT ON FORM 10-K MAY BE FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 21E OF THE SECURITIES EXCHANGE ACT OF 1934 AND SECTION 27A OF THE SECURITIES ACT OF 1933. FORWARD-LOOKING STATEMENTS INVOLVE KNOWN AND UNKNOWN RISKS AND UNCERTAINTIES WHICH MAY CAUSE BIOMERICA'S RESULTS IN FUTURE PERIODS TO DIFFER MATERIALLY FROM FORECASTED RESULTS.

LIKE OTHER BUSINESSES, WE ARE SUSCEPTIBLE TO MACROECONOMIC DOWNTURNS IN THE UNITED STATES OR ABROAD, AS WERE EXPERIENCED RECENTLY, THAT MAY AFFECT THE GENERAL ECONOMIC CLIMATE AND OUR PERFORMANCE OR OUR CUSTOMERS. ASIDE FROM GENERAL MACROECONOMIC DOWNTURNS, THE ADDITIONAL MATERIAL FACTORS, RISKS AND UNCERTAINTIES THAT COULD AFFECT FUTURE FINANCIAL RESULTS INCLUDE, BUT ARE NOT LIMITED TO: THE CONTINUED DEMAND FOR THE COMPANY'S PRODUCTS; AVAILABILITY OF RAW MATERIALS; RESULTS OF RESEARCH AND DEVELOPMENT ACTIVITIES; THE ABILITY TO RETAIN KEY EMPLOYEES AND CUSTOMERS; THE ABILITY TO COLLECT RECEIVABLES FROM CUSTOMERS; THE CONTINUED ABILITY OF THE COMPANY TO ATTAIN AND MAINTAIN THE LICENSES AND APPROVALS REQUIRED, REGIONAL OR GLOBAL PANDEMICS AND THE ECONOMIC AND SOCIAL DISRUPTIONS THESE CAUSE; TERRORIST ATTACKS AND THE IMPACT OF SUCH EVENTS; EXISTING AND POTENTIAL INCREASE IN TRADE TARIFFS, ESPECIALLY WITH CHINA, DIMINISHED OR NO ACCESS TO RAW MATERIALS THAT DIRECTLY ENTER INTO OUR MANUFACTURING PROCESS; SHIPPING LABOR DISRUPTION OR OTHER MAJOR DEGRADATION OF THE ABILITY TO SHIP OUT PRODUCTS TO END USERS; INABILITY TO SUCCESSFULLY CONTROL OUR MARGINS WHICH ARE AFFECTED BY MANY FACTORS INCLUDING COMPETITION AND PRODUCT MIX; PROTRACTED SHUTDOWN OF THE U.S. BORDER DUE TO AN ESCALATION OF TERRORIST OR COUNTER TERRORIST ACTIVITY; ANY CHANGES IN OUR BUSINESS RELATIONSHIPS WITH INTERNATIONAL DISTRIBUTORS OR THE ECONOMIC CLIMATE THEY OPERATE IN; ANY EVENT THAT HAS A MATERIAL ADVERSE IMPACT ON OUR FOREIGN MANUFACTURING OPERATIONS MAY ADVERSELY AFFECT OUR OPERATIONS AS A WHOLE; FAILURE TO MANAGE THE FUTURE EXPANSION OF OUR BUSINESS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR REVENUES AND PROFITABILITY; POSSIBLE COSTS IN COMPLYING WITH GOVERNMENT REGULATIONS AND THE DELAYS IN RECEIVING REQUIRED REGULATORY APPROVALS OR THE ENACTMENT OF NEW ADVERSE REGULATIONS OR REGULATORY REQUIREMENTS; NUMEROUS COMPETITORS, SOME OF WHICH HAVE SUBSTANTIALLY GREATER FINANCIAL AND OTHER RESOURCES THAN WE DO; POTENTIAL CLAIMS AND LITIGATION BROUGHT BY PATIENTS OR MEDICAL PROFESSIONALS ALLEGING HARM CAUSED BY THE USE OF OR EXPOSURE TO OUR PRODUCTS; RECALLS OF PRODUCTS; INABILITY TO OBTAIN FDA CLEARANCE ON PRODUCTS OR EXCESSIVE COSTS INCURRED IN ORDER TO OBTAIN SUCH APPROVALS; REGULATORY ACTIONS TAKEN BY GOVERNMENT AGENCIES SUCH AS THE FDA, SEC, USDA AND OTHER REGULATORS; QUARTERLY VARIATIONS IN OPERATING RESULTS CAUSED BY A NUMBER OF FACTORS, INCLUDING BUSINESS AND INDUSTRY CONDITIONS; AND OTHER FACTORS BEYOND OUR CONTROL. ALL THESE FACTORS MAKE IT DIFFICULT TO PREDICT OPERATING RESULTS FOR ANY PARTICULAR PERIOD.

EXCEPT AS MAY BE REQUIRED BY APPLICABLE LAW, WE MAY NOT UPDATE OR REVISE OUR FORWARD-LOOKING STATEMENTS AND THE LACK OF SUCH UPDATE DOES NOT IMPLY THAT ACTUAL EVENTS ARE AS ORIGINALLY EXPRESSED BY SUCH FORWARD-LOOKING STATEMENTS. YOU SHOULD READ THE DISCLOSURES IN THIS REPORT AND OTHER REPORTS, WHICH WE FILE WITH THE SECURITIES AND EXCHANGE COMMISSION, INCLUDING THE RISK FACTORS CONTAINED THEREIN.

## Overview

Biomerica, Inc. and its subsidiaries (which includes wholly-owned subsidiaries, Biomerica de Mexico and BioEurope GmbH), is a biomedical technology company that develops, patents, manufactures and markets advanced diagnostic and therapeutic products used at the point-of-care (physicians' offices and over-the-counter through drugstores and online) and in hospital/clinical laboratories for detection and/or treatment of medical conditions and diseases. Our diagnostic test kits are used to analyze blood, urine or fecal material from patients in the diagnosis of various diseases, food intolerances and other medical complications, or to measure the level of specific hormones, antibodies, antigens or other substances, which may exist in the human body in extremely small concentrations. The Company's products are designed to enhance the health and well-being of people, while reducing total healthcare costs.

Our primary focus is the research and development of revolutionary, patented diagnostic-guided therapy products to treat gastrointestinal diseases, such as irritable bowel syndrome, and other inflammatory diseases. These products are directed at chronic inflammatory illnesses that are widespread and common, and as such address very large markets. If these DGT products prove effective in their clinical trials, and are ultimately cleared for sale by the FDA, the revenues potential to the Company is significant.

Due to the global COVID-19 pandemic, in March 2020 we began redirecting and focused a majority of our resources to develop, test, validate, seek regulatory approval for, and sell diagnostic products that indicate if a person has been exposed to COVID-19. These diagnostic tests use a patient's blood sample to determine if the patient has certain antibodies to COVID-19 that were created as part of their body's immune response to a COVID-19 infection. During the fiscal fourth quarter, we began marketing and selling outside of the U.S. a disposable rapid finger-prick blood test, which detects COVID-19 IgG/IgM antibodies within 10 minutes. This test is designed to be performed by trained professionals anywhere, e.g. airports, schools, work, pharmacies and doctors' offices. Following fiscal 2020 year-end we submitted to the FDA an application under an EUA to sell in the U.S. a lab-scale, high throughput ELISA COVID-19 antibody test kit that would be sold to labs and hospitals to perform COVID-19 antibody testing. The Company also anticipates selling this test kit outside of the U.S. under a CE Mark. Initial sales for this product are expected during the Company's second quarter of fiscal 2021 upon EUA clearance. The Company manufactures this COVID-19 ELISA test on its automated equipment at the Company's California facility that is also used to produce serology antibody tests for other diseases. These antibody tests are designed to detect if a person has been infected by COVID-19 and mounted an immune response even if the infection was asymptomatic.

## RESULTS OF OPERATIONS

Our consolidated net sales were \$6,692,711 for fiscal 2020 compared to \$5,200,682 for fiscal 2019. This represents an increase of \$1,492,029, or 28.7%. This increase in annual sales is primarily attributable to sales of COVID-19 tests during the last quarter of the fiscal year, which offset decreases in other product lines that were negatively impacted by the COVID-19 pandemic and related national and international mandates affecting consumers. Our consolidated net sales were \$2,725,000 for the fiscal fourth quarter 2020, compared to \$1,165,860 for fiscal fourth quarter of 2019.

Consolidated cost of sales in fiscal 2020 as compared to fiscal 2019 increased from \$3,908,668 to \$4,910,935, or by \$1,002,267. The percentage of cost of sales relative to sales decreased from 75.2% to 73.4%, due to various factors, primarily due to higher margins on the COVID-19 products. Our cost of goods sold for the fiscal fourth quarter 2020 were \$1,991,378, or 73.0%, compared to \$985,053, or 84.4%, for the fourth quarter of 2019.

Consolidated selling, general and administrative costs increased in fiscal 2020 as compared to fiscal 2019 from \$2,025,706 to \$2,274,415, or by \$248,709, or 12.3%. The increase was due to increases in legal and consulting fees, personnel costs as the Company is expanding and strengthening its management team in sales and marketing, and an increase in administrative expenses due to a non-cash option expense of \$156,750 in fiscal 2020 compared to \$143,299 in the prior fiscal year. Our consolidated selling, general and administrative expenses were \$559,872 for the fiscal fourth quarter 2020, compared to \$536,816 for the fourth quarter of 2019.

Consolidated research and development expense was \$1,910,209 in fiscal 2020 as compared to \$1,679,098 in fiscal 2019, an increase of \$231,111, or 13.8%, primarily as a result of increases in costs related to the research, development and validation of COVID-19 tests, and increased costs related to our clinical trials for our InFoods® IBS product. See “Research and Development” for a more extensive description of the research being conducted. Our consolidated research and development expenses were \$661,610 for the fourth quarter of 2020, compared to \$408,810 for the fourth quarter of 2019. These costs increased in fiscal 2020 due to additional research on COVID-19 products.

Interest expense remained constant in fiscal 2020 at \$9 as compared to \$47 in fiscal 2019. Interest and dividend income for those same years increased from \$44,014 to \$71,193, respectively.

## **LIQUIDITY AND CAPITAL RESOURCES**

As of May 31, 2020, the Company had cash and cash equivalents in the amount of \$8,641,027 as compared to \$686,785 of cash and cash equivalents as of May 31, 2019. As of May 31, 2020 and 2019, the Company had working capital of \$13,289,670 and \$3,230,535, respectively.

### *Operating Activities*

During fiscal 2020, cash used in operating activities was \$4,297,498 as compared to \$2,244,039 in fiscal 2019. The factors that contributed to this were a loss of \$2,339,054, an increase in accounts receivable of \$309,090, an increase in inventories of \$717,460, and an increase in prepaid expenses of \$1,306,681, which was a result of prepayments for inventory purchase orders. These were offset by an increase in accrued compensation of \$51,798, a non-cash stock option expense of \$200,470 and depreciation and amortization of \$129,172. During fiscal 2019, the Company had a net loss of \$2,393,060 and an increase in accounts receivable of \$670,126. These were offset by an increase in accounts payable and accrued expenses of \$343,994, a non-cash stock option expense of \$151,224 and depreciation and amortization of \$162,905.

### *Investing Activities*

During fiscal 2020, cash used in investing activities was \$118,927 as compared to \$171,111 in fiscal 2019. During fiscal 2020, the Company purchased \$33,608 of property and equipment and had \$85,319 in increased intangible assets related to patents. During fiscal 2019, the Company purchased \$101,137 of property and equipment and \$69,974 in increased intangible assets related to patents.

### *Financing Activities*

Cash provided by financing activities in fiscal 2020 was \$12,373,977 as compared to \$1,907,427 in fiscal 2019. In fiscal 2020 and 2019, the Company had proceeds from the exercise of stock options of \$223,534 and \$121,790, respectively. During fiscal 2020 and 2019, the Company received \$10,232,857 and \$1,776,575, respectively, in net proceeds from the sale of common stock through the S-3 Registration Statement, net of subscriptions receivable. The common stock issued in fiscal 2020 and fiscal 2019 was issued under the S-3 “shelf” Registration Statement base prospectus filed with the SEC on June 30, 2017 and declared effective by the SEC on July 20, 2017, and under the prospectus supplement and At Market Issuance Sales Agreement, filed with the SEC on December 4, 2017 and the prospectus supplement filed with the SEC on March 20, 2020. (See Shareholders’ Equity and Subsequent Events in the notes to the consolidated financial statements for further details about SEC registrations).

On February 24, 2020, Biomerica, Inc. (the “Company”) entered into and closed on a Stock Purchase Agreement (the “Stock Purchase Agreement”) with Palm Global Small Cap Master Fund LP (“Palm”) pursuant to which the Company agreed to sell and issue to Palm, and Palm agreed to purchase from the Company, 571,429 shares of the Company’s Series A 5% Convertible Preferred Stock, \$0.08 par value per share for a purchase price of approximately \$2 million, or \$3.50 per Series A Preferred Share. Under the terms of the Stock Purchase Agreement, each share of issued Convertible Preferred Stock can be converted at any time by Palm into one share of the Company’s common stock. On March 24, 2020, Palm converted 250,000 shares of Convertible Preferred Stock into 250,000 shares of unregistered common stock. The Company received approximately \$1,917,586 in net proceeds from this sale.

The Company intends to use the net proceeds from this offering for general corporate purposes, including, without limitation, sales and marketing activities, clinical studies and product development, making acquisitions of assets, businesses, companies or securities, capital expenditures, and for working capital needs.

## Subsequent Events

On June 16, 2020, the Company announced it had submitted to the U.S. FDA an EUA application for an ELISA lab-based serology blood test for the detection of antibodies that identify if a person has been infected with COVID-19. This is the third COVID-19 antibody test introduced by the Company. The other two, which are finger-prick rapid tests, are only being sold outside of the US. The Company also intends to obtain a CE Mark to allow the sale and marketing of this ELISA laboratory test outside of the US.

On July 20, 2020, the Company filed with the SEC an S-3 registration statement that among other things registered all of the common shares issued, or to be issued, to Palm upon conversion of the Convertible Preferred Stock into common shares. The Company anticipates this registration statement shall become effective promptly following the filing of this annual report on Form 10-K with the SEC.

On July 20, 2020, the Company's outstanding Securities and Exchange Commission ("SEC") Form S-3 "Shelf" registration statement dated July 20, 2017 expired. This prior registration statement registered an indeterminate number of shares equating to a maximum aggregate offering amount of \$45,000,000 of shares.

On July 20, 2020, the Company filed with the SEC a new Form S-3 "Shelf" registration statement to replace the registration statement that expired on that day. The new registration statement registers common shares to be issued in a maximum aggregate amount of \$90,000,000. On July 27, 2020 the Company received notice from the SEC that they did not intend to review this new registration statement, and as such the Company expects this Form S-3 registration statement to be declared effective promptly following the filing of this Form 10-K. The Company filed for a larger maximum issuance amount in anticipation of the approaching completion of the Company's clinical trials for its InFoods® IBS product and the subsequent product launch that may require raising significant capital associated with this substantial opportunity to grow revenues and profits. Further, the Company's current data shows that the InFoods technology platform has great promise in diagnosing and treating several other disease states outside of IBS. The pursuit of this expanded portfolio of disease states and other opportunities may also require significant capital in the future.

On August 7, 2020, the Company received notice of allowance from the USPTO of a key patent pertaining to the Company's InFoods IBS Product. This is the second patent issued in the U.S. for the InFoods® IBS technology, and contains broad issued claims that the Company believes create strong protection for the InFoods® IBS product that is in clinical trials with several major medical institutions including Mayo Clinic, University of Texas Houston, Michigan Medicine University of Michigan, Houston Methodist and Beth Israel Deaconess Medical Center, a Harvard teaching hospital. The Company has also been issued patents for the InFoods® IBS product in Japan and Korea, and has numerous InFoods® IBS patents in review and prosecution in other countries. In addition, the Company has also filed several patents, both in the U.S. and internationally, for the InFoods® IBS technology platform that include broad claims protecting the uses of the InFoods Technology to diagnose and treat other disease states outside of IBS. Several of these patents are currently in active prosecution and review.

On August 3, 2020, the Company hired Steven Sloan, whom the Board intends to appoint as Chief Financial Officer ("CFO") on September 3, 2020, following the filing of this Form 10K. In approximately December 2019, Janet Moore, the Company's current CFO, announced to the Board her desire to retire from the Company at some point in the future once a suitable replacement could be found and hired. As such, the Company conducted an exhaustive search for a new CFO, and having determined Mr. Sloan to be an excellent candidate, hired Mr. Sloan on August 3, 2020. At the Board meeting held on August 27, 2020, the Board officially appointed and approved Mr. Sloan to serve as the Company's CFO effective September 3, 2020. Mr. Sloan's background and experience includes 13 years at General Electric with roles in internal audit, corporate finance and manufacturing finance. Most recently, Mr. Sloan spent 10 years with medical device maker Medtronic. At Medtronic, Mr. Sloan worked in four divisions over the 10 years, and most recently served as a divisional finance director. The Board is excited to have Mr. Sloan join the company as an executive officer. Janet Moore will remain an employee of the Company during a transition period.

On August 27, 2020, at a Board meeting held on that day, the Board nominated, unanimously approved and elected Cathy Coste to join the Board of Directors as a member of the Board effective September 3, 2020. Ms. Coste was elected to serve as a Board member until the Company's annual meeting in December 2020, at which time she will stand for re-election along with several other members of the Board. Ms. Coste is replacing Janet Moore, the Company's current CFO and Board member who, as previously stated, has announced her retirement from the Company and the Board and will not be standing for re-election at the upcoming annual meeting in December 2020. Cathy Coste is in the process of retiring from Deloitte and Touche where she is currently a senior partner and is an industry executive leader in Deloitte's life sciences group. During her career at Deloitte, Ms. Coste has been directly involved with over 30 life science corporations, the majority of which were large-cap and medium-cap public corporations. Ms. Coste also has extensive public company Board experience, often attending multiple Board and Board Committee meetings per month. Ms. Coste also has extensive experience in Sarbanes-Oxley compliance, corporate risk analysis and management, cyber risk assessment, fraud prevention, IT systems analysis and upgrades, internal controls and corporate governance.

On August 27, 2020, at a Board meeting held on that day, Board Member, Allen Barbieri, agreed to change from independent outside director status to become an executive director. Further, Mr. Barbieri's title was changed to Executive Vice- Chairman. As the Company's many new products, projects and opportunities have expanded, the CEO and the other members of the Board felt it was necessary to have additional executive support with managing the strategic transactions, operations and affairs of the Company, and to manage communications between the Board and management. Mr. Barbieri agreed to take on this additional responsibility.

On August 27, 2020, at a Board of Directors meeting held on that day, with the election of Ms. Coste as a member of the Board, and the designation of Mr. Barbieri as an executive Board member, the Board deemed it necessary to make certain changes to the Committees of the Board. As such, effective September 3, 2020, the following Board members will be serving in the following Board committees; 1) Audit Committee: Cathy Coste, Mark Sirgo and Jane Emerson, with Cathy Coste as the Chair of the Committee, 2) Compensation Committee: Mark Sirgo, Francis Cano and Jane Emerson, with Mark Sirgo as the Chair of the Committee, 3) Nominating and Corporate Governance Committee: Francis Cano, Cathy Coste and Jane Emerson, with Francis Cano as Chair of the Committee.

#### **OFF BALANCE SHEET ITEMS**

There were no off-balance sheet arrangements as of May 31, 2020.

#### **CRITICAL ACCOUNTING POLICIES**

The discussion and analysis of our financial condition and results of operations are based on the consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. Note 2 of the Consolidated Financial Statements describe the significant accounting policies essential to the consolidated financial statements. The preparation of these consolidated financial statements requires estimates and assumptions that affect the reported amounts and disclosures.

In general, the critical accounting policies that may require judgments or estimates relate specifically to Revenues, Allowance for Doubtful Accounts, Inventory Reserves, Stock-Based Compensation, Income Taxes, Right-of-Use Asset and Lease Liability.

We believe the following to be critical accounting policies as they require more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenues from product sales are recognized at the time the product is shipped, customarily FOB shipping point, which is when transfer of control of goods has occurred and at which point title passes. An allowance is established, if necessary, for estimated returns as revenue is recognized. Services for some contract work are invoiced and recognized for work that has been performed as the project progresses.

An allowance for doubtful accounts is established for estimated losses resulting from the inability of our customers to make required payments. The assessment of specific receivable balances and required reserves is performed by management and discussed with the audit committee. We have identified specific customers where collection is not probable and have established specific reserves, but to the extent collection is made, the allowance will be released. Additionally, if the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

Reserves are provided for excess and obsolete inventory, which are estimated based on a comparison of the quantity and cost of inventory on hand to management's forecast of customer demand. Customer demand is dependent on many factors and requires us to use significant judgment in our forecasting process. We must also make assumptions regarding the rate at which new products will be accepted in the marketplace and at which customers will transition from older products to newer products. Once a reserve is established, it is maintained until the product to which it relates is sold or otherwise disposed of, even if in subsequent periods we forecast demand for the product.

We measure stock-based compensation costs at fair value, including estimated forfeitures, and recognize the expense over the period that the recipient is required to provide service in exchange for the award, which generally is the vesting period. We use the Black-Scholes option pricing model to measure the fair value of our stock options. In determining the amount of expense to be recorded, we also estimate forfeiture rates for all awards based on historical experience to reflect the probability that employees will complete the required service period. Employee retention patterns could vary in the future and result in a change to our estimated forfeiture rate which would directly impact stock-based compensation expense.

We follow authoritative guidance to evaluate whether a valuation allowance should be established against our deferred tax assets based on the consideration of all available evidence using a "more likely than not" standard. In making such judgments, significant weight is given to evidence that can be objectively verified. We assess our deferred tax assets annually under more likely than not scenarios in which they may be realized through future income. We have determined that although we believe our net deferred tax assets of \$3,175,000 will be utilized at a future date, based on our recent losses and plans to continue our research and development, we have established a valuation allowance of \$3,175,000, which fully covers the asset.

#### Leases

During the year ended May 31, 2020, the Company adopted ASC 842, Leases. As a result, the existing deferred rent liability was netted against the Right-of-Use Asset which was capitalized at that time.

In February 2016, the Financial Accounting Standards Board issued an accounting standards update which requires lessees to recognize most leases on the balance sheet with a corresponding right-of-use asset. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. Leases will be classified as financing or operating which will drive the expense recognition pattern. For lessees, the statement of operations presentation and expense recognition pattern for financing and operating leases is similar to the current model for capital and operating leases, respectively. The Company has elected to exclude short-term leases. The update also requires additional disclosures that will better enable users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The Company adopted this guidance as of June 1, 2019, the required effective date, using the effective date transition method. As permitted under the effective date transition method, financial information and disclosure for periods prior to the date of initial application will not be updated. An adjustment to opening accumulated deficit was not required in conjunction with adoption. The adoption of this statement resulted in a right-of-use asset being recorded in the amount of \$1,942,999 and a lease liability being recorded in the amount of \$1,980,970. Both will be amortized over the life of the underlying leases. For additional information, see Note 8-Commitments and Contingencies. The Company has elected not to reassess whether expired or existing contracts contain leases, or reassess the classification of existing leases as of the adoption date. The Company leases office space and copy machines, all of which are operating leases. Most leases include the option to renew and the exercise of the renewal options is at the Company's sole discretion. Options to extend or terminate a lease are considered in the lease term to the extent that the option is reasonably certain of exercise. The leases do not include the options to purchase the leased property. The depreciable life of assets and leasehold improvements are limited by the expected lease term.

#### **RECENT ACCOUNTING PRONOUNCEMENTS**

See Note 2 to our consolidated financial statements for a listing of adopted and soon to be adopted accounting pronouncements.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not required.

#### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Exhibit 99.3, "Biomerica, Inc. and Subsidiaries Consolidated Financial Statements" is incorporated herein by this reference.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

### **ITEM 9A. CONTROLS AND PROCEDURES**

Attached as exhibits to this Form 10-K are certifications of our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”) that are required in accordance with Rule 13a-14 of the Exchange Act. This “Disclosure Controls and Procedures” section includes information concerning the controls and controls evaluation referred to in the certifications.

#### **EVALUATION OF DISCLOSURE CONTROLS**

Our management evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act as of the end of the period covered by this report. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives and the CEO and CFO have concluded that our disclosure controls and procedures are effective at the “reasonable assurance” level. Based on that evaluation the CEO and CFO concluded that information required to be disclosed in the reports that we file and submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Commission’s rules and forms; and (2) accumulated and communicated to the Company’s management, including its CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

For the reasons discussed in "Management's Report on Internal Control over Financial Reporting" below, Company management, including the CEO and CFO concluded that, as of May 31, 2020, the Company's internal control over financial reporting was effective. Management has concluded that the consolidated financial statements included in this annual report present fairly, in all material respects, the Company's financial position, results of operations, and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States of America.

#### **CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING**

There have been no changes in our internal control over financial reporting identified in connection with the evaluation that occurred during the last fiscal year that have materially affected, or that are reasonably likely to affect, our internal control over financial reporting.

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

Company management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance to the Company's management and Board of Directors regarding the reliability of financial reporting and the preparation and fair presentation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

A 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 accounting principles generally accepted in the United States of America, 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 consolidated financial statements.

The effectiveness of any system of internal control over financial reporting is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating and evaluating the controls and procedures. Because of these inherent limitations, internal control over financial reporting cannot provide absolute assurance regarding the reliability of financial reporting 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.

Company management, with the participation of the CEO and the CFO, evaluated the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13(a)-15(e) and 15(d)-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of the end of the period covered by this report. In making this assessment, Management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control - Integrated Framework (2013). Based on this assessment, management, with the participation of the CEO and CFO, believes that, as of May 31, 2020, the Company's internal control over financial reporting was effective based on those criteria.

Company management will continue to monitor and evaluate the effectiveness of its disclosure controls and procedures and its internal controls over financial reporting on an ongoing basis and are committed to taking further action and implementing improvements, as necessary and as funds allow.

Note: This 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this 10-K.

**ITEM 9B. OTHER INFORMATION.**

None.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE.**

This information is incorporated by reference to the Company's proxy statement for its 2020 Annual Meeting of Stockholders, which will be filed not later than 120 days after the end of the Company's fiscal year ended May 31, 2020.

**ITEM 11. EXECUTIVE COMPENSATION**

This information is incorporated by reference to the Company's proxy statement for its 2020 Annual Meeting of Stockholders, which will be filed not later than 120 days after the end of the Company's fiscal year ended May 31, 2020.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

This information is incorporated by reference to the Company's proxy statement for its 2020 Annual Meeting of Stockholders, which will be filed not later than 120 days after the end of the Company's fiscal year ended May 31, 2020.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

Other information regarding related transactions is incorporated by reference to the Company's proxy statement for its 2020 Annual Meeting of Stockholders, which will be filed not later than 120 days after the end of the Company's fiscal year ended May 31, 2020.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Please refer to the Company's proxy statement for its 2020 Annual Meeting of Stockholders, which will be filed not later than 120 days after the end of the Company's fiscal year ended May 31, 2020.

**PART IV**

**ITEM 15. EXHIBITS LIST AND FINANCIAL SCHEDULES**

The following documents are filed as part of this Annual Report on Form 10-K:

1. *Consolidated Financial Statements*

Reference is made to the Index to the consolidated financial statements as set forth on page FS-1 of this Annual Report on Form 10-

K.

2. *Consolidated Financial Statement Schedules*

All schedules have been omitted as the pertinent information is either not required, not applicable, or otherwise included in the financial statements and notes thereto.

3. *Exhibits*

See below.

Exhibit No.	Description
3.1	Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on September 22, 1971 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
3.2	Certificate of Amendment to Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on February 6, 1978 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
3.3	Certificate of Amendment to Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on February 4, 1983 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
3.4	Certificate of Amendment to Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on January 19, 1987 (incorporated by reference to Exhibit 3.4 filed with Form 8 Amendment No. 1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended May 31, 1987).
3.5	Certificate of Amendment of Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on November 4, 1987 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
3.6	Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
3.7	Certificate of Amendment of Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on December 20, 1994 (incorporated by reference to Exhibit 3.7 filed with Registrant's Annual Report on Form 10-KSB for the fiscal year ended May 31, 1995).
3.8	<a href="#"><u>First Amended and Restated Certificate of Incorporation of Biomerica, Inc. filed with the Secretary of State of Delaware on August 1, 2000 (incorporated by reference to Exhibit 3.8 filed with the Registrant's Annual Report on Form 10-KSB for the fiscal year ended May 31, 2000).</u></a>
4.1	Specimen Stock Certificate of Common Stock of Registrant (incorporated by reference to Exhibit 4.1 filed with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).

10.1	<a href="#">Standard Industrial/Commercial Single-Tenant Lease for 17571 Von Karman Avenue, Irvine, CA 92614, incorporated by reference to Exhibit 10.1 of the Company's August 31, 2009 Form 10Q filed October 15, 2009.</a>
10.4	2010 Stock Incentive Plan of Registrant (incorporated by reference to Exhibit 10.1 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on February 2, 2012.
10.5	2014 Stock Incentive Plan of Registrant (incorporated by reference to Exhibit 10.1 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on May 22, 2015.
10.6	2017 Stock Incentive Plan of Registrant (incorporated by reference to Exhibit 10.1 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on May 10, 2018.
10.7	2020 Stock Incentive Plan as approved by the Board on December 11, 2019, and to be voted on by shareholders at the shareholder meeting to be held December 20, 2020.
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm (PKF, LLP).</a>
31.1	<a href="#">Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2	<a href="#">Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1	<a href="#">Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2	<a href="#">Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
99.3	Biomerica, Inc. and Subsidiaries Consolidated Financial Statements
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

The certifications attached as Exhibits 32.1 and 32.2 accompany this Annual Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the registrant for purposes of Section 18 of the Exchange Act and are not to be incorporated by reference into any of the registrant’s filings under the Securities Act or the Exchange Act, irrespective of any general incorporation language contained in any such filing.

**SIGNATURES**

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**BIOMERICA, INC.**

Registrant

By /s/ Zackary S. Irani

Zackary S. Irani,  
Chief Executive Officer

Dated: August 31, 2020

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature and Capacity

<u>/s/ Zackary S. Irani</u> Zackary S. Irani Director, Chief Executive Officer	Date: 8/31/20
<u>/s/ Janet Moore</u> Janet Moore, Secretary, Director, Chief Financial Officer	Date: 8/31/20
<u>/s/ Francis R. Cano, Ph.D.</u> Francis R. Cano, Ph.D. Director	Date: 8/31/20
<u>/s/ Allen Barbieri</u> Allen Barbieri Director, Audit Committee Member	Date: 8/31/20
<u>/s/ Jane Emerson, M.D., Ph.D.</u> Jane Emerson, M.D., Ph.D. Director, Audit Committee Member	Date: 8/31/20
<u>/s/ Mark Sirgo, Pharm.D</u> Mark Sirgo, Pharm.D., Audit Committee Member Director	Date: 8/31/20

**BIOMERICA, INC. AND SUBSIDIARIES**  
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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders  
Biomerica, Inc. and Subsidiaries  
Irvine, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Biomerica, Inc. (a Delaware Corporation) and Subsidiaries (the “Company”) as of May 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, shareholders’ equity, and cash flows for each of the two years in the period ended May 31, 2020, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of May 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended May 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/PKF, LLP

We have served as the Company’s auditor since 2004.

San Diego, California  
August 31, 2020

**BIOMERICA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**

	May 31, 2020	May 31, 2019
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 8,641,027	\$ 686,785
Accounts receivable, less allowance for doubtful accounts of \$70,981 and \$73,110, respectively	1,765,871	1,454,652
Inventories, net	2,850,836	2,151,090
Prepaid expenses and other	1,509,083	202,402
Total current assets	<u>14,766,817</u>	<u>4,494,929</u>
<b>PROPERTY AND EQUIPMENT:</b>		
Equipment	1,921,833	1,891,381
Furniture, fixtures and leasehold improvements	225,189	222,033
Total property and equipment	2,147,022	2,113,414
Accumulated depreciation	(1,867,643)	(1,762,344)
Net property and equipment	279,379	351,070
INTANGIBLE ASSETS, net of accumulated amortization	168,655	107,209
RIGHT OF USE ASSETS, net of accumulated amortization	1,711,510	--
INVESTMENTS	165,324	165,324
OTHER ASSETS	168,193	126,832
TOTAL ASSETS	<u>\$ 17,259,878</u>	<u>\$ 5,245,364</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 986,711	\$ 1,037,565
Accrued compensation	278,627	226,829
Lease liability, current portion	211,809	--
Total current liabilities	1,477,147	1,264,394
Lease liability, net of current portion	1,569,678	--
Total liabilities	<u>3,046,825</u>	<u>1,264,394</u>
<b>COMMITMENTS AND CONTINGENCIES (NOTE 8)</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Preferred stock, Series A 5%, convertible, \$0.08 par value, 571,429 shares authorized, 321,429 issued and outstanding at May 31, 2020 and no shares authorized, issued and outstanding at May 31, 2019	25,714	--
Preferred stock, undesignated, no par value, authorized 4,428,571 and 5,000,000 shares, at May 31, 2020 and May 31, 2019, respectively and none issued and outstanding at May 31, 2020 and May 31, 2019	--	--
Common stock, \$.08 par value; 25,000,000 shares authorized; 11,740,089 and 9,677,188 shares issued and outstanding at May 31, 2020 and 2019, respectively	939,205	774,173
Additional paid-in capital	35,213,707	22,830,006
Accumulated other comprehensive loss	(39,841)	(36,531)
Accumulated deficit	(21,925,732)	(19,586,678)
Total shareholders' equity	<u>14,213,053</u>	<u>3,980,970</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 17,259,878</u>	<u>\$ 5,245,364</u>

See accompanying notes to consolidated financial statements.

**BIOMERICA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

FOR THE YEARS ENDED MAY 31,	2020	2019
Net sales	\$ 6,692,711	\$ 5,200,682
Cost of sales	(4,910,935)	(3,908,668)
<b>GROSS PROFIT</b>	<b>1,781,776</b>	<b>1,292,014</b>
<b>OPERATING EXPENSES:</b>		
Selling, general and administrative	2,274,415	2,025,706
Research and development	1,910,209	1,679,098
<b>Total operating expenses</b>	<b>4,184,624</b>	<b>3,704,804</b>
<b>LOSS FROM OPERATIONS</b>	<b>(2,402,848)</b>	<b>(2,412,790)</b>
<b>OTHER INCOME (EXPENSE):</b>		
Interest expense	(9)	(47)
Interest and dividend income	71,193	44,014
<b>Total other income</b>	<b>71,184</b>	<b>43,967</b>
<b>LOSS BEFORE INCOME TAXES</b>	<b>(2,331,664)</b>	<b>(2,368,823)</b>
<b>INCOME TAX EXPENSE</b>	<b>(7,390)</b>	<b>(24,237)</b>
<b>NET LOSS</b>	<b>\$ (2,339,054)</b>	<b>\$ (2,393,060)</b>
<b>BASIC NET LOSS PER COMMON SHARE</b>	<b>\$ (0.23)</b>	<b>\$ (0.26)</b>
<b>DILUTED NET LOSS PER COMMON SHARE</b>	<b>\$ (0.23)</b>	<b>\$ (0.26)</b>
<b>WEIGHTED AVERAGE NUMBER OF COMMON AND COMMON EQUIVALENT SHARES</b>		
Basic	10,166,296	9,212,557
Diluted	10,166,296	9,212,557
<b>NET LOSS</b>	<b>\$ (2,339,054)</b>	<b>\$ (2,393,060)</b>
<b>OTHER COMPREHENSIVE LOSS:</b>		
Foreign currency translation	(3,310)	(10,395)
<b>COMPREHENSIVE LOSS</b>	<b>\$ (2,342,364)</b>	<b>\$ (2,403,455)</b>

See accompanying notes to consolidated financial statements.

**BIOMERICA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**YEARS ENDED MAY 31, 2020 AND 2019**

	Common Stock		Series A 5% Convertible Preferred Stock		Additional Paid-in Capital	Subscriptions Receivable	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount					
Balances, May 31, 2018	8,888,011	\$ 711,040	--	\$ --	\$ 20,843,550	\$ (9,062)	\$ (26,136)	\$ (17,193,618)	\$ 4,325,774
Exercise of stock options	163,500	13,080	--	--	108,710	--	--	--	121,790
Net proceeds from ATM	625,677	50,053	--	--	1,726,522	--	--	--	1,776,575
Stock subscription receivable	--	--	--	--	--	9,062	--	--	9,062
Foreign currency translation	--	--	--	--	--	--	(10,395)	--	(10,395)
Compensation expense in connection with options granted	--	--	--	--	151,224	--	--	--	151,224
Net loss	--	--	--	--	--	--	--	(2,393,060)	(2,393,060)
Balances, May 31, 2019	9,677,188	774,173	--	--	22,830,006	--	(36,531)	(19,586,678)	3,980,970
Exercise of stock options	137,958	11,037	--	--	212,497	--	--	--	223,534
Net proceeds from ATM	1,674,943	133,995	--	--	10,098,862	--	--	--	10,232,857
Issuance of preferred stock	--	--	571,429	45,714	1,871,872	--	--	--	1,917,586
Foreign currency translation	--	--	--	--	--	--	(3,310)	--	(3,310)
Conversion of preferred to common stock	250,000	20,000	(250,000)	(20,000)	--	--	--	--	--
Compensation expense in connection with options granted	--	--	--	--	200,470	--	--	--	200,470
Net loss	--	--	--	--	--	--	--	(2,339,054)	(2,339,054)
Balances, May 31, 2020	11,740,089	\$ 939,205	321,429	\$ 25,714	\$ 35,213,707	\$ --	\$ (39,841)	\$ (21,925,732)	\$ 14,213,053

See accompanying notes to consolidated financial statements.

**BIOMERICA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

For the Years Ended May 31,	2020	2019
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,339,054)	\$ (2,393,060)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	129,172	162,905
Change in provision for allowance for doubtful accounts	(2,129)	15,415
Inventory reserve	17,714	6,300
Stock option expense	200,470	151,224
Reduction (increase) in deferred rent liability	(37,971)	6,615
Decrease in deferred tax asset	--	10,000
Amortization of right-of-use asset	269,460	--
Changes in assets and liabilities:		
Accounts receivable	(309,090)	(670,126)
Inventories	(717,460)	21,387
Prepaid expenses and other	(1,306,681)	98,007
Reduction in lease liability	(199,483)	--
Other assets	(41,361)	(13,677)
Accounts payable and accrued expenses	(12,883)	343,994
Accrued compensation	51,798	16,977
Net cash used in operating activities	<u>(4,297,498)</u>	<u>(2,244,039)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Increase in intangibles	(85,319)	(69,974)
Purchases of property and equipment	(33,608)	(101,137)
Net cash used in investing activities	<u>(118,927)</u>	<u>(171,111)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Common stock subscribed	--	9,062
Proceeds from sale of convertible preferred stock, net	1,917,586	--
Proceeds from sales of common stock, net	10,232,857	1,776,575
Proceeds from exercise of stock options	223,534	121,790
Net cash provided by financing activities	<u>12,373,977</u>	<u>1,907,427</u>
Effect of exchange rate changes on cash	(3,310)	(10,395)
Net increase (decrease) in cash and cash equivalents	7,954,242	(518,118)
CASH AND CASH EQUIVALENTS, beginning of year	686,785	1,204,903
CASH AND CASH EQUIVALENTS, end of year	<u>\$ 8,641,027</u>	<u>\$ 686,785</u>
<b>SUPPLEMENTAL DISCLOSURE OF CASH-FLOW INFORMATION</b>		
Cash paid during the year for:		
Interest	\$ 9	\$ 47
Income taxes	<u>\$ 7,390</u>	<u>\$ 14,237</u>
Non-cash Investing and Financing Activities:		
Establishment of Right-of-use asset per ASC 842	<u>\$ 1,942,999</u>	<u>--</u>
Establishment of Lease liability per ASC 842	<u>\$ 1,980,970</u>	<u>--</u>

The accompanying notes are an integral part of these statements.

**BIOMERICA, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**YEARS ENDED MAY 31, 2020 AND 2019**

**1. ORGANIZATION**

Biomerica Inc. and Subsidiaries (collectively the “Company”, “we”, “us”, or “our”) develops, patents, manufactures and markets advanced diagnostic and therapeutic products used at the point-of-care (physicians' offices and over-the-counter through drugstores and online) and in hospital/clinical laboratories for detection and/or treatment of medical conditions and diseases. Our diagnostic test kits are used to analyze blood, urine or fecal material from patients in the diagnosis of various diseases, food intolerances and other medical complications, or to measure the level of specific hormones, antibodies, antigens or other substances, which may exist in the human body in extremely small concentrations. The Company's products are designed to enhance the health and well-being of people, while reducing total healthcare costs.

Our primary focus is the research and development of revolutionary, patented diagnostic guided therapy (“DGT”) products to treat gastrointestinal diseases, such as irritable bowel syndrome, and other inflammatory diseases. These products are directed at chronic inflammatory illnesses that are widespread and common, and as such address very large markets. If these DGT products prove effective in their clinical trials, and are ultimately cleared for sale by the U.S. Food and Drug Administrations (“FDA”), the revenues potential to the Company is significant.

Due to the global 2019 SARS-CoV-2 novel coronavirus (“COVID-19”) pandemic, in March 2020 we began redirecting and focused a majority of our resources to develop, test, validate, seek regulatory approval for, and sell diagnostic products that indicate if a person has been exposed to COVID-19.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**PRINCIPLES OF CONSOLIDATION**

The enclosed consolidated financial statements for the years ended May 31, 2020 and 2019 include the accounts of Biomerica, Inc. (“Biomerica”) as well as its German subsidiary (BioEurope GmbH) and Mexican subsidiary (Biomerica de Mexico). All significant intercompany accounts and transactions have been eliminated in consolidation.

**ACCOUNTING ESTIMATES**

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reported period. Estimates that are made include the allowance for doubtful accounts, which is estimated based on current as well as historical past practices with a customer; stock option forfeiture rates, which are calculated based on historical data; and inventory obsolescence, which are based on projected and historical usage of materials; and lease liability and right-of-use assets, which are calculated based on certain assumptions such as borrowing rate, likelihood of lease extensions to occur, asset valuation, among other things; (and other items that may be necessary to estimate using current, historical and judgment based). Actual results could materially differ from those estimates.

**FAIR VALUE OF FINANCIAL INSTRUMENTS**

The Company has financial instruments whereby the fair market value of the financial instruments could be different than that recorded on a historical basis. The Company's financial instruments consist of its cash and cash equivalents, accounts receivable, and accounts payable. The carrying amounts of the Company's financial instruments approximate their fair values.

**CONCENTRATION OF CREDIT RISK**

The Company maintains cash balances at certain financial institutions in excess of amounts insured by federal agencies. As of May 31, 2020, the Company had approximately \$8,595,241 of uninsured cash. The Company does not believe it is exposed to any significant credit risks.

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The Company provides credit in the normal course of business to customers throughout the United States and in foreign markets. The Company performs ongoing credit evaluations of its customers and requires accelerated prepayment in some circumstances.

For the years ended May 31, 2020 and 2019, the Company had three distributors and two distributors which accounted for a total of 57.2% and 46.3% of our net consolidated sales, respectively. Of this, for the years ended May 31, 2020 and 2019 one of the distributors mentioned above accounted for 25.7% and 36.3%, respectively, of net consolidated sales. At May 31, 2020 and 2019, the Company had three distributors and two distributors which accounted for a total of 80.0% and 68.1%, respectively, of gross accounts receivable. Of the 80.0% as of May 31, 2020, 43.9% was owed by a distributor in Ecuador. Total gross receivables at May 31, 2020 and 2019 were \$1,836,852 and \$1,527,762, respectively.

For the year ended May 31, 2020, one vendor accounted for 59.3% of the purchases of raw materials. For the year ended May 31, 2019, two vendors accounted for a total of 23.8 % of the purchases of raw materials.

### **GEOGRAPHIC CONCENTRATION**

As of May 31, 2020 and 2019, approximately \$613,000 and \$665,000 of Biomerica's gross inventory and approximately \$31,000 and \$39,000, of Biomerica's property and equipment, net of accumulated depreciation, was located in Mexicali, Mexico, respectively.

### **CASH AND CASH EQUIVALENTS**

Cash and cash equivalents consist of demand deposits and money market accounts with original maturities of less than three months.

### **ACCOUNTS RECEIVABLE**

The Company extends unsecured credit to its customers on a regular basis. International accounts are required to prepay until they establish a history with the Company and at that time, they are extended credit at levels based on a number of criteria. Based on various criteria, initial credit levels for individual distributors are approved by designated officers and managers of the company. All increases in credit limits are also approved by designated upper level management. Management evaluates receivables on a quarterly basis and adjusts the allowance for doubtful accounts accordingly. Balances over ninety days old are usually reserved for unless collection is reasonably assured.

Occasionally certain long-standing customers, who routinely place large orders, will have unusually large receivables balances relative to the total gross receivables. Management monitors the payments for these large balances closely and very often requires payment of existing invoices before shipping new sales orders.

### **INVENTORIES**

The Company values inventory at the lower of cost (determined using a combination of specific lot identification and the first-in, first-out methods) or net realizable value. Management periodically reviews inventory for excess quantities and obsolescence. Management evaluates quantities on hand, physical condition, and technical functionality as these characteristics may be impacted by anticipated customer demand for current products and new product introductions. The reserve is adjusted based on such evaluation, with a corresponding provision included in cost of sales. Abnormal amounts of idle facility expenses, freight, handling costs and wasted material are recognized as current period charges and the allocation of fixed production overhead is based on the normal capacity of the production facilities.

Inventories approximate the following at May 31:

	2020	2019
Raw materials	\$ 1,635,000	\$ 1,208,000
Work in progress	988,000	771,000
Finished products	228,000	172,000
Total	\$ 2,851,000	\$ 2,151,000

Reserves for inventory obsolescence are recorded as necessary to reduce obsolete inventory to estimated net realizable value or to specifically reserve for obsolete inventory that the Company intends to dispose of. As of May 31, 2020 and 2019, inventory reserves were approximately \$67,000 and \$49,000, respectively.

## **PROPERTY AND EQUIPMENT**

Property and equipment are stated at cost. Expenditures for additions and major improvements are capitalized. Repairs and maintenance costs are charged to operations as incurred. When property and equipment are sold, retired or otherwise disposed of, the related cost and accumulated depreciation or amortization are removed from the accounts, and gains or losses from sales, retirements and dispositions are credited or charged to income.

Depreciation and amortization are provided over the estimated useful lives of the related assets, ranging from 5 to 10 years, using the straight-line method. Leasehold improvements are amortized over the lesser of the estimated useful life of the asset or the term of the lease. Depreciation and amortization expense on property and equipment amounted to \$105,299 and \$101,216 for the years ended May 31, 2020 and 2019, respectively.

## **INTANGIBLE ASSETS**

Intangible assets include trademarks, product rights, technology rights and patents, and are accounted for based on Accounting Standards Codification (“ASC”), ASC 350 Intangibles – Goodwill and Other (“ASC 350”). In that regard, intangible assets that have indefinite useful lives are not amortized but are tested at least annually for impairment or more frequently if events or changes in circumstances indicate that the asset might be impaired.

Intangible assets are being amortized using the straight-line method over the useful life, not to exceed 18 years for marketing and distribution rights, 10 years for purchased technology use rights, and 20 years for patents. Amortization amounted to \$23,873 and \$61,689 for the years ended May 31, 2020 and 2019, respectively.

The Company assesses the recoverability of these intangible assets by determining whether the amortization of the asset's balance over its remaining life can be recovered through projected undiscounted future cash flows. The Company uses a qualitative assessment to determine whether there was any impairment. No impairment adjustment was required as of May 31, 2020 or 2019.

## **INVESTMENTS**

From time-to-time, the Company makes investments in privately-held companies. The Company determines whether the fair values of any investments in privately-held entities have declined below their carrying value whenever adverse events or changes in circumstances indicate that recorded values may not be recoverable. If the Company considers any such decline to be other than temporary (based on various factors, including historical financial results, and the overall health of the investee’s industry), a write-down to estimated fair value is recorded. Investments represent the Company’s investment in a Polish distributor which is primarily engaged in distributing medical products and devices. The Company currently has not written down the investment and no events have occurred which could indicate the carrying value of the investment to be greater than the fair value. The Company owns approximately 6% of the investee and, accordingly, applies the cost method to account for the investment. Under the cost method, investments are recorded at cost, with gains and losses recognized as of the sale date, and income recorded when received.

## **SHARE-BASED COMPENSATION**

The Company follows the guidance of the accounting provisions of ASC 718, Share-based Compensation (“ASC 718”), which requires the use of the fair-value based method to determine compensation for all arrangements under which employees and others receive shares of stock or equity instruments (options). The fair value of each option award is estimated on the date of grant using the Black-Scholes options-pricing model that uses assumptions for expected volatility, expected dividends, expected forfeiture rate, expected term, and the risk-free interest rate. The Company has not paid dividends historically and does not expect to pay them in the future. Expected volatilities are based on weighted averages of the historical volatility of the Company’s common stock estimated over the expected term of the options. The expected forfeiture rate is based on historical forfeitures experienced. The expected term of options granted is derived using the “simplified method” which computes expected term as the average of the sum of the vesting term plus the contract term as historically the Company had limited activity surrounding its options. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term.

The Company has not paid dividends historically and does not expect to pay them in the foreseeable future.

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In applying the Black-Scholes options-pricing model, assumptions used were as follows:

	2020	2019
Dividend yield	0%	0%
Expected volatility	55.52-72.62%	57.90-60.41%
Risk free interest rate	0.43-1.80%	2.33-2.85%
Expected life	3.75-6.25 years	3.75-6.25 years

### REVENUE RECOGNITION

The Company has various contracts with customers. All of the contracts specify that revenues from product sales are recognized at the time the product is shipped, customarily FOB shipping point, which is when the transfer of control of goods has occurred and at which point title passes. The Company does not allow for returns except in the event of defective merchandise and therefore does not establish an allowance for returns. In addition, the Company has contracts with customers wherein they receive purchase discounts for achieving specified sales volumes. The Company evaluated the status of these contracts as of May 31, 2020 and does not believe that any additional discounts will be given through the end of the contract periods. Services for some contract work are invoiced and recognized for work that has been performed as the project progresses. The Company sells clinical lab products to domestic and international distributors, including hospitals and clinical laboratories, medical research institutions, medical schools and pharmaceutical companies. OTC products are sold directly to drug stores and e-commerce customers as well as to distributors. Physicians' office products are sold to physicians and distributors, all of whom are categorized below according to the type of products sold to them. We also manufacture certain components on a contract basis for domestic and international manufacturers.

Disaggregation of revenue:

The following is a breakdown of revenues according to markets to which the products are sold:

	Year Ended	
	May 31, 2020	May 31, 2019
Clinical Lab	\$ 2,922,425	\$ 4,043,993
OTC	1,269,535	868,605
Physicians' Office	2,194,991	170,871
Contract Manufacturing	305,760	117,213
Total	\$ 6,692,711	\$ 5,200,682

See Note 7 for additional information regarding revenue concentrations.

### SHIPPING AND HANDLING FEES

The Company includes shipping and handling fees billed to customers in net sales.

### RESEARCH AND DEVELOPMENT

Research and development costs are expensed as incurred. The Company expensed \$1,910,209 and \$1,679,098 of research and development costs during the years ended May 31, 2020 and 2019, respectively.

## INCOME TAXES

The Company accounts for income taxes in accordance with ASC 740, Income Taxes (“ASC 740”). Deferred tax assets and liabilities arise from temporary differences between the tax bases of assets and liabilities and their reported amounts in the consolidated financial statements that will result in taxable or deductible amounts in future years and the benefits of net operating loss and tax credit carryforwards. These temporary differences and the benefits of net operating loss and tax credit carryforwards are measured using enacted tax rates. A valuation allowance is recorded to reduce deferred tax assets to the extent that management considers it is more likely than not that a deferred tax asset will not be realized. In determining the valuation allowance, the Company considers factors such as the reversal of deferred income tax assets, projected taxable income, and the character of income tax assets and tax planning strategies. A change to these factors could impact the estimated valuation allowance and income tax expense. At May 31, 2020 and 2019, in accordance with ASC 740, the Company has a valuation allowance for substantially all of its deferred tax assets. During the fiscal year ended May 31, 2020, this valuation allowance was increased to approximately \$3,175,000, which fully covers the net tax asset of \$3,175,000.

The Company accounts for its uncertain tax provisions by using a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not, based solely on the technical merits, that the position will be sustained in an audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the appropriate amount of the benefit to recognize. The amount of benefit to recognize is measured as the maximum amount which is more likely than not to be realized. The tax position is derecognized when it is no longer more likely than not capable of being sustained. On subsequent recognition and measurement the maximum amount which is more likely than not to be recognized at each reporting date will represent the Company’s best estimate, given the information available at the reporting date, although the outcome of the tax position is not absolute or final. Upon adopting the revisions in ASC 740, the Company elected to follow an accounting policy to classify accrued interest related to liabilities for income taxes within the “Interest expense” line and penalties related to liabilities for income taxes within the “Other expense” line of the consolidated statements of operations and comprehensive loss.

## ADVERTISING COSTS

The Company reports the cost of all advertising as expense in the period in which those costs are incurred. Advertising costs were approximately \$174 and \$0 for the years ended May 31, 2020 and 2019, respectively.

## FOREIGN CURRENCY TRANSLATION

The subsidiary located in Mexico operates primarily using the Mexican peso. The subsidiary located in Germany operates primarily using the U.S. dollar, with an immaterial amount of transactions occurring using the Euro. Accordingly, assets and liabilities of these subsidiaries are translated using exchange rates in effect at the end of the year, and revenues and costs are translated using average exchange rates for the year. The resulting adjustments to assets and liabilities are presented as a separate component of accumulated other comprehensive loss. There are no adjustments to foreign currency loss that are included in the consolidated statements of operations for the years ended May 31, 2020 and 2019.

## RIGHT-OF-USE ASSETS AND LEASE LIABILITY

Incentive payments received from landlords are recorded as deferred lease incentives and are amortized over the underlying lease term on a straight-line basis as a reduction of rent expense. When the terms of an operating lease provide for periods of free rent, rent concessions, and/or rent escalations, the Company establishes a deferred rent liability for the difference between the scheduled rent payment and the straight-line rent expense recognized. This deferred rent liability was amortized over the underlying lease term on a straight-line basis as a reduction of rent expense. During the year ended May 31, 2020, the Company adopted ASC 842, Leases. As a result, the existing deferred rent liability was netted against the Right-of-Use Asset which was capitalized at that time.

In February 2016, the Financial Accounting Standards Board (“FASB”) issued an accounting standards update which requires lessees to recognize most leases on the balance sheet with a corresponding right-of-use asset. Right-of-use assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Right-of-Use assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. Leases will be classified as financing or operating which will drive the expense recognition pattern. For lessees, the statement of operations presentation and expense recognition pattern for financing and operating leases is similar to the current model for capital and operating leases, respectively. The Company has elected to exclude short-term leases. The update also requires additional disclosures that will better enable users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The Company adopted this guidance as of June 1, 2019, the required effective date, using the effective date transition method. As permitted under the effective date transition method, financial information and disclosure for periods prior to the date of initial application will not be updated. An adjustment to opening accumulated deficit was not required in conjunction with adoption. The adoption of this statement resulted in a right-of-use asset being recorded in the amount of \$1,942,999 and a lease liability being recorded in the amount of \$1,980,970. Both will be amortized over the life of the underlying leases. For additional information, see Note 8-Commitments and Contingencies. The Company has elected not to reassess whether expired or existing contracts contain leases, or reassess the classification of existing leases as of the adoption date. The Company leases office space and copy machines, all of which are operating leases. Most leases include the option to renew and the exercise of the renewal options is at the Company’s sole discretion. Options to extend or terminate a lease are considered in the lease term to the extent that the option is reasonably certain of exercise. The leases do not include the options to purchase the leased property. The depreciable life of assets and leasehold improvements are limited by the expected lease term.

**NET LOSS PER SHARE**

Basic loss per share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Diluted loss per share reflects the potential dilution that could occur from common shares issuable through stock options, warrants and other convertible securities using the treasury stock method. The total amounts of anti-dilutive stock options not included in the loss per share calculation for the years ended May 31, 2020 and 2019 were 1,789,251 and 1,476,209, respectively.

The Company also has outstanding 321,429 of Series A 5% Convertible Preferred Stock, which may be converted at any time to common stock.

**SEGMENT REPORTING**

ASC 280, Segment Reporting (“ASC 280”), establishes standards for reporting, by public business enterprises, information about operating segments, products and services, geographic areas, and major customers. The Company’s operations are analyzed by management and its chief operating decision maker as being part of a single industry segment: the design, development, marketing and sales of diagnostic kits.

**REPORTING COMPREHENSIVE LOSS**

Comprehensive loss represents net loss and any revenues, expenses, gains and losses that, under GAAP, are excluded from net loss and recognized directly as a component of shareholders’ equity. Accumulated other comprehensive loss consists solely of foreign currency translation adjustments.

**RECENT ACCOUNTING PRONOUNCEMENTS**

On February 15, 2018, the FASB issued ASU 2018-02, “Reclassification of Certain Tax Effects From Accumulated Comprehensive Income” (“ASU 2018-02”). ASU 2018-02 will give companies the option to reclassify stranded tax effects caused by the newly-enacted U.S. Tax Cuts and Jobs Act (“TCJA”) from accumulated other comprehensive income (“ASCI”) to retained earnings. ASU 2018-02 was effective for all companies for the fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Management is taking the provisions of this statement into account in the preparation of the consolidated financial statements for the year ended May 31, 2020. The adoption of this standard has not had a significant impact on the Company’s consolidated financial statements.

On June 20, 2018, the FASB issued ASU 2018-07, “Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting” (“ASU 2018-07”). ASU 2018-07 is intended to reduce cost and complexity and to improve financial reporting for share-based payments to nonemployees (service providers, external legal counsel, and suppliers). ASU 2018-07 was effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. During the year ended May 31, 2020, the Company adopted the provisions of this statement and is taking them into account in the preparation of the consolidated financial statements for the year ended May 31, 2020. The adoption of this standard has not had a significant impact on the Company’s consolidated financial statements.

Other recent ASU’s issued by the FASB and guidance issued by the Securities and Exchange Commission (“SEC”) did not, or are not believed by management to, have a material effect on the Company’s present or future consolidated financial statements.

**3. INTANGIBLE ASSETS, NET**

Intangible assets, net of accumulated amortization, consist of the following at May 31:

	2020	2019
Licenses	\$ 551,397	\$ 510,600
Patents	113,382	68,860
Less accumulated amortization- licenses	(487,989)	(471,530)
Less accumulated amortization- patents	(8,135)	(721)
Intangible assets, net	\$ 168,655	\$ 107,209

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Expected amortization of intangible assets for the years ending May 31:

2021	\$	18,112
2022		8,503
2023		6,211
2024		6,136
2025		5,219
Thereafter		124,474
Total	\$	168,655

**4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

The Company's accounts payable and accrued expense balances consist of the following at May 31:

	2020	2019
Accounts payable and accrued expenses	\$ 986,711	\$ 999,594
Deferred rent	-	37,971
	\$ 986,711	\$ 1,037,565

As of May 31, 2020 and 2019 the Company had two vendors and one vendor which accounted for 26.9% and 32.1%, respectively, of accounts payable.

**5. SHAREHOLDERS' EQUITY**

On February 24, 2020, the Company filed with the Secretary of State of Delaware a certificate of designation to authorize for issuance 571,429 shares of Series A 5% Convertible Preferred Stock. On February 26, 2020, the Company filed with the Secretary of State of Delaware a certificate of correction, correcting certain language defects in the previously filed certificate of designation. Please see below a description of the Series A 5% Convertible Preferred Stock shares that were issued in February 2020.

**STOCK OPTION AND RESTRICTED STOCK PLANS**

In August 2010, the Company adopted a stock option and restricted stock plan (the "2010 Plan") which provides that non-qualified options and incentive stock options and restricted stock covering an aggregate of 850,000 shares of the Company's unissued common stock may be granted to affiliates, employees or consultants of the Company. This plan was approved by shareholders in December 2010. The 2010 Plan expires in December 2020. Options granted under the 2010 Plan will be granted at prices not less than 80% of the then fair market value of the common stock and will expire not more than 10 years after the date of grant.

In December 2014, the Company adopted a stock option and restricted stock plan (the "2014 Plan") which provides that non-qualified options and incentive stock options and restricted stock covering an aggregate of 850,000 shares of the Company's unissued common stock may be granted to affiliates, employees or consultants of the Company. This plan was approved by shareholders in December 2014. The 2014 Plan expires in December 2024. Options granted under the 2014 Plan will be granted at prices not less than 80% of the then fair market value of the common stock and will expire not more than 10 years after the date of grant.

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In December 2017, the Company adopted a stock option and restricted stock plan (the “2017 Plan”) which provides that non-qualified options and incentive stock options and restricted stock covering an aggregate of 900,000 shares of the Company’s unissued common stock may be granted to affiliates, employees or consultants of the Company. This plan was approved by shareholders in December 2017. The 2017 Plan expires in December 2027. Options granted under the 2017 Plan will be granted at prices not less than 80% of the then fair market value of the common stock and will expire not more than 10 years after the date of grant.

In February 2020, the Board approved the 2020 Stock Incentive Plan (the “2020 Plan”), which will be presented to the Company’s shareholders for final approval and adoption at the Company’s annual meeting to be held in December 2020. The 2020 Plan authorizes the issuance of an aggregate number of common stock options and/or restricted common shares to be issued in an amount not to exceed 900,000. The 2020 Plan authorizes the issuance of common stock options and restricted common shares to employees, directors and consultants of the Company. During fiscal 2020, certain common stock options were granted under this plan, the actual vesting of which is subject to the plan being approved and adopted by shareholders at our upcoming annual meeting of shareholders.

Stock option expense during fiscal 2020 was \$200,470. This included, by department, \$17,892 for research and development, \$156,750 in administrative, \$2,933 in sales and marketing, \$22,895 for production and \$0 in Mexico. In fiscal 2019, stock option expense was \$151,224. This included \$3,714 in research and development, \$143,299 in administrative, \$4,163 in sales and marketing and \$48 in Mexico.

Activity as to aggregate stock options outstanding is as follows:

	NUMBER OF STOCK OPTIONS	EXERCISE PRICE RANGE PER SHARE	WEIGHTED AVERAGE EXERCISE PRICE
Options outstanding at May 31, 2018	1,138,625	\$0.71-\$3.90	\$ 1.65
Options granted	558,000	\$2.25-\$3.62	\$ 2.60
Options exercised	(163,500)	\$0.71-\$1.04	\$ 0.76
Options canceled or expired	(56,916)	\$0.71-\$3.62	\$ 2.49
Options outstanding at May 31, 2019	1,476,209	\$0.82-\$3.90	\$ 2.07
Options granted	517,500	\$2.68-\$8.18	\$ 4.47
Options exercised	(137,958)	\$0.82-\$3.90	\$ 1.64
Options canceled or expired	(66,500)	\$0.85-\$8.18	\$ 3.43
Options outstanding at May 31, 2020	1,789,251	\$0.82-\$8.18	\$ 2.75

The weighted average fair value of options granted during 2020 and 2019 was \$4.47 and \$2.60, respectively. The aggregate intrinsic value of options exercised during 2020 and 2019 was approximately \$589,000 and \$364,000, respectively. The aggregate intrinsic value of options outstanding at May 31, 2020 and 2019 was approximately \$6,923,000 and \$808,000, respectively. The aggregate intrinsic value of options vested and exercisable at May 31, 2020 and 2019 was approximately \$4,442,000 and \$685,000, respectively.

Number of non-vested stock options included in table above is as follows:

	NUMBER OF SHARES	STOCK OPTIONS WEIGHTED AVERAGE GRANT DATE FAIR VALUE
Non-vested shares at May 31, 2019	769,584	\$ 2.49
Granted	517,500	\$ 4.47
Vested	(407,750)	\$ 2.25
Forfeited	(56,750)	\$ 3.55
Non-vested shares at May 31, 2020	822,584	\$ 3.78

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At May 31, 2020, total compensation cost related to non-vested stock option awards not yet recognized totaled approximately \$663,000. The weighted-average period over which this amount is expected to be recognized is 3.67 years. The weighted average remaining contractual term of options that were exercisable at May 31, 2020 was 6.19 years.

The following summarizes information about all of the Company's stock options outstanding at May 31, 2020. These options are comprised of those granted under the 2010, 2014, 2017 and 2020 plans.

RANGE OF EXERCISE PRICES	NUMBER OUTSTANDING May 31, 2020	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE IN YEARS	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER EXERCISABLE AT MAY 31, 2020	WEIGHTED AVERAGE EXERCISE PRICE
\$ 0.82-\$1.04	276,000	4.44	\$0.84	276,000	\$0.84
\$ 1.20-\$ 2.81	1,072,500	7.57	\$2.17	506,000	\$1.71
\$ 3.62-\$ 8.18	440,751	7.62	\$5.38	184,667	\$3.87

#### COMMON STOCK ACTIVITY

During the year ended May 31, 2020, options to purchase 137,958 shares of common stock were exercised at prices ranging from \$0.82 to \$3.90. Total net proceeds to the Company were \$223,534.

During the year ended May 31, 2019, options to purchase 163,500 shares of common stock were exercised at prices ranging from \$0.71 to \$1.04. Total net proceeds to the Company were \$121,790.

On December 1, 2017, the Company entered into an At Market Issuance Sales Agreement (or "ATM Agreement") with an agent, and filed a prospectus supplement with the SEC pursuant to which the Company could offer and sell from time to time up to an aggregate of \$7,000,000 of shares of the Company's common stock, par value \$0.08 per share (the "Placement Shares"), through the agent. From December 1, 2017 to March 19, 2020, the Company sold common stock resulting in \$6,997,935 of gross proceeds under this ATM Agreement, of which \$3,771,048 were sold during the year ended May 31, 2020. This At Market Issuance Agreement expired on July 20, 2020 upon the expiration of the Company's S-3 registration statement base prospectus dated July 20, 2017.

The Placement Shares sold and issued under the ATM Agreement have been registered under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to the Registration Statement on Form S-3 (File No. 333-219130) (the "Registration Statement"), which was originally filed with the SEC on June 30, 2017 and declared effective by the SEC on July 20, 2017, the base prospectus contained within the Registration Statement, and the prospectus supplement related to the sale of shares under the ATM Agreement was filed with the SEC on December 1, 2017.

On March 20, 2020, the Company filed a new prospectus supplement to the S-3 registration statement base prospectus dated July 20, 2017 for purposes of raising up to \$12,500,000 from time to time pursuant to the terms of the ATM Agreement. This ATM Agreement expired on July 20, 2020 upon the expiration of the Company's S-3 registration statement base prospectus dated July 20, 2017. Gross proceeds for the year ended May 31, 2020, were \$6,817,330.

Please refer to "Subsequent Events" for a description of the Form S-3 filed with the Securities and Exchange Commission on July 20, 2020.

Combined Placement Shares sold under the ATM during the twelve months ended May 31, 2020 under the two prospectus supplements dated December 1, 2017 and March 20, 2020 totaled 1,674,943 shares. Total net proceeds from the sale of Placement Shares under the two prospectus supplements during the twelve months ended May 31, 2020 were \$10,232,857 after deducting commissions for each sale and legal, accounting, and other fees related to the filing of the Form S-3. These shares were sold at prices ranging from \$2.33 to \$9.08 per share.

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Under an ATM Agreement, sales of the Placement Shares are deemed to be “at the market offering” as defined in Rule 415 promulgated under the Securities Act. The agent acts as sales agent under the ATM and uses commercially reasonable efforts to sell on the Company’s behalf all of the Placement Shares requested to be sold from time to time by the Company, consistent with its normal trading and sales practices, on mutually agreed terms between the agent and the Company.

The Company has no obligation to sell any of the Placement Shares under the ATM Agreement, and may at any time suspend offers under, or terminate the ATM Agreement.

During the year ended May 31, 2020, 250,000 shares of common stock were converted from Preferred Stock as described below in “Preferred Stock Activity”.

During the year ended May 31, 2020, the Company sold 1,674,943 shares of its common stock at prices ranging from \$2.33 to \$9.08 under its S-3 Registration Statement which resulted in gross proceeds of \$10,588,378 and net proceeds to the Company of \$10,232,857 after deducting commissions for each sale and legal, accounting and other fees related to the filing of the Form S-3.

During the year ended May 31, 2019, the Company sold 625,677 shares of its common stock at prices ranging from \$2.59 to \$4.16 under its S-3 Registration Statement which resulted in gross proceeds of \$1,847,662 and net proceeds to the Company of \$1,776,575 after deducting commissions for each sale and legal, accounting and other fees related to the filing of the Form S-3.

### **PREFERRED STOCK ACTIVITY**

On February 24, 2020, the Company entered into and closed on a Stock Purchase Agreement (the “Stock Purchase Agreement”) with Palm Global Small Cap Master Fund LP (“Palm”) pursuant to which the Company agreed to sell and issue to Palm, and Palm agreed to purchase from the Company, 571,429 shares of the Company’s Series A 5% Convertible Preferred Stock, \$0.08 par value per share for a purchase price of approximately \$2 million, or \$3.50 per Series A Convertible Preferred Stock. Under the terms of the Stock Purchase Agreement, each share of issued Convertible Preferred Stock can be converted at any time by Palm into one share of the Company’s common stock, subject to certain adjustments.

The Series A 5% Convertible Preferred Stock shares are convertible at the option of the holder at any time into an equal number of common stock shares (“Conversion Shares”). The conversion price may be adjusted for stock splits or other common stock issuances. The Company may require the conversion of all of the outstanding Series A 5% Convertible Preferred Stock shares if the closing sale price of the Company’s common stock equals or exceeds \$9.00 for a period of five consecutive trading days with a minimum average trading volume of 35,000 shares per day over such period; provided, that, on such date, the Conversion Shares are registered for resale.

The Series A 5% Convertible Preferred Stock shares accrue annual preferred dividends at a rate of \$0.175 per Series A 5% Convertible Preferred Stock share. The shares of Series A 5% Convertible Preferred Stock are also entitled to receive participating dividends. The shares of Series A 5% Convertible Preferred Stock have no voting rights. Accruing dividends are payable only when, as, and if declared by the Board and the Company has no obligation to pay such accruing dividends. As such, since the dividend payment is conditional on events that are deemed unlikely at this time, a liability has not been recorded at year-end for these dividends. Dividends that have accumulated through May 31, 2020 total approximately \$18,000.

The 5% dividend is a cumulative dividend, and is only payable if the Board elects to pay a dividend on the Company’s common shares, at which point the accrued cumulative dividend must be paid current. At the conversion of any preferred shares into common shares, all accrued, unpaid dividends on the converted preferred shares are canceled and forgiven by Palm. As part of the purchase, Palm was given the right to appoint a Board Observer to the Board. The preferred shares have many material preferential rights over common shareholders in the event of a filing for bankruptcy or dissolution of the Company. For further details on the rights of these preferred shares, please refer to the Company’s disclosures filed under an SEC 8-K on February 26, 2020.

On March 24, 2020, Palm converted 250,000 shares of Convertible Preferred Stock into 250,000 shares of unregistered common stock. On July 21, 2020, the Company filed with the SEC a registration statement on Form S-3 that among other things registered all of the common shares issued, or to be issued, to Palm upon conversion of the Convertible Preferred Stock into common shares. The Company anticipates the registration statement shall become effective promptly following the filing of this annual report on Form 10-K with the SEC. The Company incurred approximately \$82,000 in issuance costs associated with this stock issuance.

### **6. INCOME TAXES**

Income tax expense from continuing operations for the years ended May 31, 2020 and 2019 consists of the following:

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Years ended May 31,	2020	2019
<b>Current:</b>		
U.S. Federal	\$ --	\$ --
Foreign Taxes Subsidiaries	(6,590)	(13,437)
State and local	(800)	(800)
<b>Total current</b>	<b>(7,390)</b>	<b>(14,237)</b>
<b>Deferred:</b>		
U.S. Federal	--	(10,000)
State and local	--	--
<b>Total deferred</b>	<b>--</b>	<b>(10,000)</b>
Income tax expense	\$ (7,390)	\$ (24,237)

Income tax expense from continuing operations differs from the amounts computed by applying the U.S. Federal income tax rate applicable for each year (21% for 2020 and 2019) to pretax income as a result of the following:

Years ended May 31,	2020	2019
<b>Computed "expected" tax benefit</b>	<b>\$ 489,651</b>	<b>\$ 497,453</b>
Increase (reduction) in income taxes resulting from:		
Change in valuation allowance	(716,000)	(910,000)
State income taxes, net of federal benefit	154,254	89,267
Research and development tax credits	49,770	55,908
Permanent tax differences and other	21,525	(256,572)
Foreign taxes of subsidiaries	(6,590)	(13,437)
Income tax expense	\$ (7,390)	\$ (24,237)

The tax effect of significant temporary differences is presented below:

As of May 31,	2020	2019
<b>Deferred tax assets:</b>		
Accounts receivable, principally due to allowance for doubtful accounts	\$ 17,000	\$ 18,000
Inventory valuation	16,000	12,000
Compensated absences	64,000	48,000
Net operating loss carryforwards	2,286,000	1,735,000
Tax credit carryforwards	599,000	467,000
Deferred rent expense/Capitalized leases	17,000	9,000
Other	171,000	176,000
Accumulated depreciation and amortization	5,000	(6,000)
Total deferred tax assets	3,175,000	2,459,000
Less valuation allowance	(3,175,000)	(2,459,000)
Net deferred tax asset	\$ --	\$ --

The Company has provided a valuation allowance of approximately \$3,175,000 and \$2,459,000 as of May 31, 2020 and 2019, respectively. The net change in the valuation allowance for the years ended May 31, 2020 and 2019 was an increase of \$716,000 and \$900,000, respectively.

At May 31, 2020, the Company has Federal income tax NOL carryforwards of approximately \$9,213,000. At May 31, 2020, the Company has California state income tax net operating loss carryforwards of approximately \$5,025,000.

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At May 31, 2020, the Company has Federal research and development tax credit carryforward of approximately \$438,000. The Federal credits begin to expire in 2027. The Company also had similar credit carryforwards for state purposes of \$160,000 at May 31, 2020.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss ("NOL") and credit carryforwards may be limited by statute because of a cumulative change in ownership of more than 50%. Pursuant to Sections 382 and 383 of the IRC, the annual use of the Company's NOLs and credit carryforwards would be limited if there is a cumulative change of ownership (as that term is defined in Section 382(g) of the IRC of greater than 50% in a three-year period. Management has not performed an analysis to determine if the Company has had a cumulative change in ownership of greater than 50%.

For the year ended May 31, 2020, the Company did an analysis of its ASC 740 position and has not identified any uncertain tax positions as defined under ASC 740. Should such position be identified in the future and should the Company owe interest and penalties as a result of this, these would be recognized as interest expense and other expense, respectively, in the consolidated financial statements. The Company is no longer subject to any significant U.S. federal tax examinations by tax authorities for years before fiscal year 2016.

## 7. GEOGRAPHIC INFORMATION

The Company operates as one segment. Geographic information regarding net sales is approximately as follows:

Years ended May 31,	2020	2019
<b>Net sales:</b>		
Europe	\$ 2,434,000	\$ 1,694,000
United States	445,000	523,000
Asia	1,867,000	2,514,000
South America	1,615,000	256,000
Middle East	314,000	214,000
Other foreign	18,000	--
Total net sales	\$ 6,693,000	\$ 5,201,000

## 8. COMMITMENTS AND CONTINGENCIES

### OPERATING LEASES

On June 18, 2009, the Company entered into an agreement to lease a building in Irvine, California. The lease commenced September 1, 2009 and ended August 31, 2016. On November 30, 2015, the Company entered into the First Amendment to Lease wherein it exercised its option to extend its lease until August 31, 2021. The initial base rent for the lease extension was \$21,000 per month, increasing to \$23,637 through August 31, 2021. The monthly rent is currently \$22,948. The security deposit of \$22,080 remains the same.

In November 2016, the Company's subsidiary, Biomerica de Mexico, entered into a ten-year lease for approximately 8,104 square feet at a monthly rent of \$2,926. The Company has one 10-year option to renew at the end of the initial lease period. The yearly rate is subject to an annual adjustment for inflation according to the United States Bureau of Labor Statistics Consumer Price Index for All Urban Consumers. The monthly rate is currently \$3,239. Biomerica, Inc. is not a guarantor of such lease.

Total gross rent expense in the U.S. for fiscal 2020 was \$300,267 and 2019 was \$268,550. Rent expense for the Mexico facility for fiscal 2020 and 2019 was \$43,481 and \$46,040, respectively.

For purposes of determining straight-line rent expense, the lease term is calculated from the date the Company first takes possession of the facility, including any periods of free rent and any renewal options periods that the Company is reasonably certain of exercising. The Company's office and equipment leases generally have contractually specified minimum rent and annual rent increases are included in the measurement of the right-of-use asset and related lease liability. Additionally, under these lease arrangements, the Company may be required to pay directly, or reimburse the lessors, for some maintenance and operating costs. Such amounts are generally variable and therefore not included in the measurement of the right-of-use asset and related lease liability but are instead recognized as variable lease expense in the Condensed Consolidated Statements of Operations and Comprehensive Loss when they are incurred.

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Supplemental cash flow information related to leases for the year ended May 31, 2020:

Operating cash flows from operating leases	\$	311,742
Right-of-use assets obtained in exchange for new operating lease liabilities		--
Weighted average remaining lease term (in years)		6.27
Weighted average discount rate		6.5%

The maturity of lease liabilities as of May 31, 2020 are as follows:

Years ending May 31,		
2021	\$	211,808
2022		236,391
2023		262,810
2024		291,329
2025		322,098
Thereafter		457,051
Total	\$	1,781,487

According to the terms of the lease in Irvine, the Company is also responsible for routine repairs of the building and for certain increases in property tax.

The Company also has various insignificant leases for office equipment.

#### RETIREMENT SAVINGS PLAN

Effective September 1, 1986, the Company established a 401(k) plan for the benefit of its employees. The plan permits eligible employees to contribute to the plan up to the maximum percentage of total annual compensation allowable under the limits of IRC Sections 415, 401(k) and 404. The Company, at the discretion of its Board of Directors, may make contributions to the plan in amounts determined by the Board each year. No contributions by the Company have been made since the plan's inception.

#### LITIGATION

The Company is, from time to time, involved in legal proceedings, claims and litigation arising in the ordinary course of business. While the amounts claimed may be substantial, the ultimate liability cannot presently be determined because of considerable uncertainties that exist. Therefore, it is possible the outcome of such legal proceedings, claims and litigation could have a material effect on quarterly or annual operating results or cash flows when resolved in a future period. However, based on facts currently available, management believes such matters will not have a material adverse effect on the Company's consolidated financial position, results of operations or cash flows. There were no legal proceedings pending as of May 31, 2020.

On July 2, 2020, we received a notice of investigation and subpoena to produce information and documents from the Division of Enforcement of the SEC. The subpoena seeks information and documents related to events and circumstances leading up to our March 17, 2020 announcement that we had commenced shipping samples of our COVID-19 IgG/IgM Rapid Test to countries outside of the United States, and had initiated the application process with the United States Food and Drug Administration under the COVID-19 Emergency Use Authorization for approval to market and sell the test in the United States. The subpoena also seeks information and documents about the identity of any persons who were aware of the substance of the March 17, 2020 announcement prior to that date. We are cooperating and intends to continue cooperating fully with the SEC's investigation. At this time, we are unable to predict the duration, scope or outcome of this investigation.

## CONTRACTS

### Contracts and Licensing Agreements

The Company has one royalty agreement in which it has obtained rights to manufacture and market certain products for the life of the products. Royalty expense of approximately \$15,000 and \$19,000 is included in cost of sales for the agreement for each of the years ended May 31, 2020 and 2019, respectively. Sales of products manufactured under these agreements comprise approximately 1.8% and 2.9% of total sales for the years ended May 31, 2020 and 2019, respectively. The Company may license other products or technology in the future as it deems necessary for conducting business. The Company has other royalty agreements, however they are not considered material.

On May 25, 2016, the Company entered into an Exclusive Marketing License Agreement (“Telcon Agreement”) with Celtis Pharm Co., Ltd., who subsequently changed their name to Telcon Pharmaceutical Co., LTD (“Telcon”), a medical company in the South Korea. The Telcon Agreement grants to Telcon an exclusive license to market and sell Biomerica’s new InFoods® IBS products (“IBS Products”) in South Korea. The term of the agreement is for a period of five years following Korean FDA clearance of the product and provides an additional two years for Telcon to attain such Korean FDA clearance. The sequential two-year and five-year terms do not begin until after Biomerica first receives final clearance for sale of the IBS Products in the United States from the FDA. Telcon, at its sole cost and expense, must use its commercially reasonable good faith efforts to obtain Korean FDA for the IBS Product to be sold in South Korea. The agreement may be cancelled if Biomerica has not obtained final USFDA clearance for sale of the IBS Products on or before December 31, 2019. Biomerica is also obligated to maintain a full quality assurance system for the IBS Products following the harmonized standards according to Annex IV of Directive 98/79/EC. We are working with Telcon management to extend the term of the Telcon Agreement.

The terms of the Telcon Agreement provide up to \$1.25 million in exclusivity fees based on certain milestones including Biomerica’s starting clinical trials in the United States, receipt of US FDA clearance and Telcon’s first sales of IBS Products in Korea. If Biomerica commences FDA Trials and Telcon pays the initial \$250,000 milestone-based exclusivity fees, and the Agreement is subsequently terminated by either party for lack of performance, then Biomerica shall issue to Telcon 83,333 shares of Biomerica common in consideration for the \$250,000 of paid exclusivity fee. No exclusivity fees have yet been paid.

Additionally, the Telcon Agreement provides for a royalty of 15% paid to Biomerica on all sales in Korea of the IBS Product, and further sets the pricing of IBS Products sold to Telcon. In order to retain the exclusivity within South Korean, Telcon must meet certain annual minimum royalty payments to Biomerica following Telcon’s receipt of Korean FDA approval or clearance for the IBS Product to be sold in Korea, which in no case will be later than May 31, 2019. In September 2017, an agreement to extend this date was signed extending the date until April 30, 2020. We are working with Telcon management to extend the date for the completion of this obligation.

In October 2018, the Company entered into an agreement with a customer for the sale of its EZ Detect product in the United States. The term of the Agreement is for three years and is renewable for one-year terms upon written notice. The agreement defines the price and rebate to the customer. There were no sales under this agreement in fiscal 2020.

In December 2018, the Company entered into an agreement with a company for the purpose of procuring and assisting in transactions related to its EZ Detect product with China. The contract is for a period of twelve months and is cancellable by either party with forty-five days written notice. The contract specifies 2.5-6% success fees and milestone payments upon certain events transpiring. During fiscal 2019, the Company incurred \$27,579 in expenses for this contract. There were no expenses incurred in fiscal 2020.

In April 2019, the Company entered into a consulting agreement with the former, retired president of the Company. The agreement stipulates that he shall be available by consultation if needed for the period of April 8, 2019 through April 7, 2020. In return, the Company has agreed to allow his stock options in the Company to continue to vest and be exercisable until April 7, 2020. At that time, no options will vest and any vested, unexercised options must be exercised by July 2, 2020 at which time they will be forfeited. All options that were eligible to vest according to this agreement were vested and exercised. There were no fees incurred for this agreement for consultation services.

In May 2019, the Company entered into an agreement with MaxHealth Medical International Limited and MaxHealth China (“MaxHealth”) giving MaxHealth exclusive distribution rights to Biomerica’s EZ Detect Product in China. Among other things, the Agreement called for MaxHealth to deposit \$100,000 upon execution of the agreement, and an additional \$900,000 (for a total of \$1,000,000 USD) upon clearance of Chinese customs of the initial order of \$100,000. The \$1,000,000 was to be used as a prepayment for the first \$1,000,000 of purchase orders for the product. While the Company received the first deposit of \$100,000, and shipped \$100,000 of product to Maxhealth, the Company has not received the second deposit, and has not shipped any further product, which has placed MaxHealth in Default of the agreement. MaxHealth and the Company have been negotiating a possible remedy for the default. There is no assurance these negotiations will be successful or that the default will be rectified.

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On April 1, 2020, the Company entered into two separate non-exclusive license agreements (the “Mount Sinai License Agreements”) with the Mount Sinai Icahn School of Medicine in New York (“Mount Sinai”) to license technology from Mount Sinai that the Company intends to use to scale up and manufacture a laboratory version serological test for SARS-CoV-2 coronavirus. This test uses the ELISA microplate format that can run on existing open system equipment found in most hospitals and clinical laboratories in the United States. The non-exclusive Mount Sinai License Agreements provide for royalty payments to Mount Sinai based on a percentage of gross sales of commercial products manufactured and sold by Biomerica that incorporate the Mount Sinai technology licensed under the Mount Sinai License Agreement. On June 20, 2020, the Company filed for EUA with the FDA based on this on this technology. The Company purchased materials in the amount of \$5,100 during fiscal 2020 and subsequently to that another \$2,850. No royalty fees have been paid yet on these agreements.

On May 7, 2020, the Company entered into an exclusive license agreement (the “UC License Agreements”) with The Regents of the University of California (“UC”) to license all patent rights pertaining to certain licensed technology from UC. This technology is being developed at the University by one of the professors and his team utilizing CRISPR technology. This group is developing a viral detection test for SARS-CoV-2 coronavirus. If this technology development is successful, the Company will work with the University to transfer the technology to Biomerica where the CRISPR based product will need to be further developed, validated and cleared with regulatory agencies for commercial sale into the market. The exclusive UC License Agreements provide for an initial and annual license fee, and a royalty payment on all commercial revenues, to the UC Regents. The UC License Agreement also includes certain investment requirements and milestones the Company will need to meet for the launch of a commercial product based on the licensed technology. The Company paid an initial license fee of \$5,000 with the execution of the agreement. An additional \$5,000 is due in September 2020. No royalties have been paid yet on this agreement. A license maintenance fee of \$10,000 is due annually. This is creditable against earned royalties due each year in the amount of five percent on net sales of licensed products.

On May 18, 2020, the Company signed a non-exclusive distributor agreement with a company in Russia for the distribution of COVID-19 tests. The term of the agreement is for an initial two years, however, the agreement may be terminated for breach of contract. The agreement allows for quantity discounts based on certain milestones.

### **Clinical Trial Agreements**

In September 2017, the Company signed a Clinical Samples Agreement with the University of Southern California for the purpose of providing clinical samples for use by the Company in conducting future clinical trials for one of the products which the Company is developing. The initial budget was estimated to be \$82,472. The work started in October 2017 with charges for work performed being invoiced and paid monthly. This study ended in February 2020. The Company incurred \$2,200 in fiscal 2020 and \$12,567 in expenses previously invoiced for a total of \$14,767. In addition, \$17,064 in fees has been accrued for unbilled charges as of May 31, 2020.

In November 2017, the Company entered into a Clinical Trial Agreement with the University of Michigan to perform an InFoods 24 Endpoint Determination Study. The Company will be invoiced monthly for work performed the previous month. The maximum budget for the study is \$181,015. The Company incurred \$30,900 and \$40,885 in expenses for this study during fiscal 2020 and 2019, respectively. This commitment is approximately 47% billed.

In January 2018, the Company entered into a Clinical Trial Agreement with Beth Israel Deaconess Medical Center for the purposes of conducting an Antibody Guided Restriction Trial Using Biomerica InFoods 24G Test in patients with a previous diagnosis of Irritable Bowel Syndrome (“IBS”). The study began in the first quarter of fiscal 2019. The Company was invoiced monthly for work performed the previous month. The total cost of the study was initially estimated to be \$142,000, however the study was expanded and total costs of the trial was approximately \$305,000. The Company incurred \$141,640 and \$146,760 in expenses for this study during fiscal 2020 and 2019, respectively. This study was closed in February 2020 and no additional costs are expected.

On July 12, 2019, the Company entered into a Clinical Trial Agreement with a research management institution for the purpose of conducting a clinical trial of the Biomerica HP Stool Antigen test. The term of the agreement shall be until completion of the work outlined and the charges will be invoiced monthly for work performed in the previous month. The maximum budgeted costs was approximately \$117,200. During fiscal 2020, \$13,111 in charges were billed and the Company accrued \$6,670 in charges as of May 31, 2020. This study is now closed so no further charges will be incurred.

On July 22, 2019, the Company entered into a Clinical Trial Agreement with a research institution, for the purpose of conducting a clinical trial of the Biomerica Infoods product. The term of the agreement shall be until completion of the work outlined and the charges will be invoiced monthly for work performed in the previous month. The maximum budgeted costs will be approximately \$107,000. The Company incurred \$20,875 in charges during fiscal 2020. This commitment is approximately 19% billed. In addition, the Company accrued \$2,650 in unbilled charges as of May 31, 2020.

On September 25, 2019, the Company entered into a Clinical Trial Agreement with a medical practice for the purpose of conducting a clinical trial of the Biomerica Infoods IBS product. The term of the agreement shall be until completion of the work outlined and the charges will be invoiced monthly for work performed in the previous month. The maximum budgeted costs will be \$136,000. During fiscal 2020, the Company was invoiced \$45,250 in expenses. This commitment is approximately 33% billed. In addition, the Company accrued \$5,975 in unbilled charges as of May 31, 2020.

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On September 25, 2019, the Company entered into a Clinical Trial Agreement with a research institution for the purpose of conducting a clinical trial of the Biomerica H. pylori product. The term of the agreement shall be until completion of the work outlined and the charges were invoiced monthly for work performed in the previous month. The maximum budgeted costs will be approximately \$57,800. The Company was invoiced \$41,845 in charges during the year ended May 31, 2020. At May 31, 2020, the commitment was approximately 72% billed and the study has been closed so no further charges will be incurred.

In December 2019, the Company entered into a Clinical Trial Agreement with Houston Methodist Research Institute for the purpose of conducting a clinical trial of the Biomerica InFoods® IBS product. The term of the agreement shall be until completion of the work outlined and the charges will be invoiced monthly for work performed in the previous month. The maximum budgeted costs will be approximately \$133,000. During the year ended May 31, 2020, the Company was invoiced \$4,000 in charges. This commitment is approximately 3% billed.

On May 28, 2020, the Company entered into a Clinical Trial Agreement with the Mayo Clinic Arizona for the purpose of participating in the ongoing end point clinical trial of the Biomerica InFoods IBS product. The term of the agreement shall be until completion of the work outlined and the charges will be invoiced monthly for work performed in the previous month. The maximum budgeted costs will be \$135,515. At May 31, 2020, \$17,390 had been invoiced to the Company. This commitment is approximately 13% billed.

On May 28, 2020, the Company entered into a Clinical Trial Agreement with the Mayo Clinic Jacksonville for the purpose of participating in the ongoing end point clinical trial of the Biomerica InFoods IBS product. The term of the agreement shall be until completion of the work outlined and the charges will be invoiced monthly for work performed in the previous month. The maximum budgeted costs will be \$135,515. The Company has not received any billings as of May 31, 2020, however accrued \$17,390 in charges as of that date.

The addition of both Mayo Clinic sites and other major medical centers were brought into the InFoods® IBS clinicals studies in order to accelerate patient enrollment.

### **9. SUBSEQUENT EVENTS**

Subsequent to May 31, 2020 and through August 31, 2020, 12,500 stock options were exercised at \$1.20 per share. Net proceeds to the Company were approximately \$14,900.

On June 15, 2020, the Board approved the grant of 52,000 stock options to certain employees. The options vest one-quarter on June 15, 2021 and then one-quarter per year thereafter. The options have an exercise price of \$5.46 per share and have a ten-year life.

On July 13, 2020, the Board approved the grant of 76,000 stock options to certain employees and consultants. The options vest one-quarter on July 13, 2021 and then one-quarter per year thereafter. The options have an exercise price of \$8.70 per share and have a ten-year life.

On July 13, 2020, the approved the grant of 7,500 stock options to a consultant. The options vest one-half on January 13, 2021 and one-half on July 13, 2021. The options have an exercise price of \$8.70 per share and have a ten-year life.

On June 25, 2020, the Company entered into a Clinical Trial Agreement with the University of Texas Health Science Center for the purpose of conducting a clinical trial of the Biomerica InFoods product. The term of the agreement shall be until completion of the work outlined and the charges will be invoiced monthly for work performed in the previous month. The maximum budgeted costs will be \$139,850.

On July 20, 2020, the Company filed with the SEC a new Form S-3 “Shelf” registration statement to replace the registration statement that expired on that day. The new registration statement registers common shares to be issued in a maximum aggregate of \$90,000,000.

On August 27, 2020, the Board approved the grant of 33,000 stock options to an employee and a board member. The options vest one-quarter on August 27, 2021 and then one-quarter per year thereafter. The options have an exercise price of \$7.47 per share and have a ten-year life.

On August 27, 2020, the Board approved the grant of 2,500 stock options to a consultant. The options vest one-half on January 13, 2021 and 50% on July 13, 2021. The options have an exercise price of \$7.47 per share and have a ten-year life.

**EXHIBIT A**  
**BIOMERICA, INC.**  
**2020 STOCK INCENTIVE PLAN**

**ARTICLE 1. INTRODUCTION.**

The Plan was adopted by the Board effective February 10, 2020, and submitted to shareholders for approval at the Biomerica Annual Shareholder meeting in December, 2020. The purpose of the Plan is to promote the long-term success of the Company and the creation of stockholder value by (a) encouraging Employees, Outside Directors and Consultants to focus on critical long-range objectives, (b) encouraging the attraction and retention of Employees, Outside Directors and Consultants with exceptional qualifications and (c) linking Employees, Outside Directors and Consultants directly to stockholder interests through increased stock ownership. The Plan seeks to achieve this purpose by providing for Awards in the form of Restricted Shares or Options (which may constitute incentive stock options or non-statutory stock options).

The Plan shall be governed by, and construed in accordance with, the laws of the State of California.

**ARTICLE 2. ADMINISTRATION.**

2.1 COMMITTEE COMPOSITION. The Plan shall be administered by the Board of Directors of the Company, provided the Board may delegate administration of the Plan to a Committee consisting exclusively of two or more Outside Directors of the Company, who shall be appointed by the Board. In addition, the composition of the Committee shall satisfy:

(a) Such requirements as the Securities and Exchange Commission may establish for administrators acting under plans intended to qualify for exemption under Rule 16b-3 (or its successor) under the Exchange Act; and

(b) Such requirements as the Internal Revenue Service may establish for outside directors acting under plans intended to qualify for exemption under Section 162(m)(4)(C) of the Code.

2.2 COMMITTEE RESPONSIBILITIES. The Board (or the Committee, if applicable) shall (a) review management's recommendation as to the Employees, Outside Directors and Consultants who are to receive Awards under the Plan, (b) determine the type, number, vesting requirements and other features and conditions of such Awards, (c) interpret the Plan and (d) make all other decisions relating to the operation of the Plan. The Board and Committee may adopt such rules or guidelines as it deems appropriate to implement the Plan. The Board's and Committee's determinations under the Plan shall be final and binding on all persons.

2.3 COMMITTEE FOR NON-OFFICER GRANTS. The Board may also appoint a secondary committee of the Board, which shall be composed of one or more directors of the Company who need not satisfy the requirements of Section 2.1. Such secondary committee may administer the Plan with respect to Employees and Consultants who are not considered officers or directors of the Company under section 16 of the Exchange Act or covered employees under Section 162(m)(3) of the Code, may grant Awards under the Plan to such Employees and Consultants and may determine all features and conditions of such Awards. Within the limitations of this Section 2.3, any reference in the Plan to the Committee shall include such secondary committee.

**ARTICLE 3. SHARES AVAILABLE FOR GRANTS.**

3.1 BASIC LIMITATION. Common Shares issued pursuant to the Plan may be authorized but unissued shares or treasury shares. The aggregate number of Options and Restricted Shares awarded under the Plan shall not exceed NINE HUNDRED THOUSAND (900,000). The limitations of this Section 3.1 and Section 3.2 shall be subject to adjustment pursuant to Article 9.

3.2 ADDITIONAL SHARES. If Options are forfeited or terminate for any other reason before being exercised, then the corresponding Common Shares shall again become available for the grant of Options or Restricted Shares under the Plan. If Restricted Shares or Common Shares issued upon the exercise of Options are forfeited, then such Common Shares shall again become available for the grant of NSOs and Restricted Shares under the Plan. The aggregate number of Common Shares that may be issued under the Plan upon the exercise of ISOs shall not be increased when Restricted Shares or other Common Shares are forfeited.

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#### **ARTICLE 4. ELIGIBILITY.**

4.1 NONSTATUTORY STOCK OPTIONS AND RESTRICTED SHARES. Only Employees, Outside Directors and Consultants shall be eligible for the grant of NSOs and Restricted Shares.

4.2 INCENTIVE STOCK OPTIONS. Only Employees who are employees of the Company, a Parent or a Subsidiary shall be eligible for the grant of ISOs. In addition, an Employee who owns more than 10% of the total combined voting power of all classes of outstanding stock of the Company or any of its Parents or Subsidiaries shall not be eligible for the grant of an ISO unless the requirements set forth in section 422(c)(5) of the Code are satisfied.

#### **ARTICLE 5. OPTIONS.**

5.1 STOCK OPTION AGREEMENT. Each grant of an Option under the Plan shall be evidenced by a Stock Option Agreement between the Optionee and the Company. Such Option shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan. The provisions of the various Stock Option Agreements entered into under the Plan need not be identical. A Stock Option Agreement may provide that a new Option will be granted automatically to the Optionee when he or she exercises a prior Option and pays the Exercise Price in the form described in Section 6.2.

5.2 NUMBER OF SHARES. Each Stock Option Agreement shall specify the number of Common Shares subject to the Option and shall provide for the adjustment of such number in accordance with Article 9. The limitations set forth in the preceding sentence shall be subject to adjustment in accordance with Article 9.

5.3 EXERCISE PRICE. Each Stock Option Agreement shall specify the Exercise Price; provided that the Exercise Price under an ISO shall in no event be less than 100% of the Fair Market Value of a Common Share on the date of grant and the Exercise Price under an NSO shall in no event be less than 85% of the Fair Market Value of a Common Share on the date of grant. In the case of an NSO, a Stock Option Agreement may specify an Exercise Price that varies in accordance with a predetermined formula while the NSO is outstanding.

5.4 VESTING, EXERCISABILITY AND TERM. Unless otherwise approved by the Board of Directors and provided in the Stock Option Agreement, an Optionee's right to exercise the Option shall vest pro rata over a period of four (4) years, with 25% of the Option vesting on each of the first, second, third and fourth anniversaries of the date of grant. The Stock Option Agreement shall also specify the term or expiration of the Option; provided that the term of an ISO shall in no event exceed 10 years from the date of grant. A Stock Option Agreement may provide for accelerated exercisability in the event of the Optionee's death, disability or retirement or other events and may provide for expiration prior to the end of its term in the event of the termination of the Optionee's service.

5.5 EFFECT OF CHANGE IN CONTROL. Notwithstanding Section 5.4 above, each Option shall automatically fully vest (e.g., become exercisable) as to all or part of the Common Shares subject to such Option in the event that a Change in Control (as defined in Section 14.4 below) occurs with respect to the Company, subject to the following limitations.

5.6 MODIFICATION OR ASSUMPTION OF OPTIONS. Within the limitations of the Plan, the Board or the Committee may modify, extend or assume outstanding options or may accept the cancellation of outstanding options (whether granted by the Company or by another issuer) in return for the grant of new options for the same or a different number of shares and at the same or a different exercise price. The foregoing notwithstanding, no modification of an Option shall, without the consent of the Optionee, alter or impair his or her rights or obligations under such Option.

5.7 BUYOUT PROVISIONS. The Committee may at any time (a) offer to buy out for a payment in cash or cash equivalents an Option previously granted or (b) authorize an Optionee to elect to cash out the vested portion of an Option previously granted, in either case at such time and based upon such terms and conditions as the Board or the Committee shall establish.

**ARTICLE 6. PAYMENT FOR OPTION SHARES.**

6.1 GENERAL RULE. The entire Exercise Price of Common Shares issued upon exercise of Options shall be payable in cash or cash equivalents at the time when such Common Shares are purchased, except as follows:

(a) In the case of an ISO granted under the Plan, payment shall be made only pursuant to the express provisions of the applicable Stock Option Agreement. The Stock Option Agreement may specify that payment may be made in any form(s) described in this Article 6.

(b) In the case of an NSO, the Committee may at any time accept payment in any form(s) described in this Article 6.

6.2 EXERCISE/SALE. To the extent that this Section 6.2 is applicable, all or any part of the Exercise Price and any withholding taxes may be paid by delivering (on a form prescribed by the Company) an irrevocable direction to a securities broker approved by the Company to sell all or part of the Common Shares being purchased under the Plan and to deliver all or part of the sales proceeds to the Company.

6.3 EXERCISE/PLEDGE. To the extent that this Section 6.3 is applicable, all or any part of the Exercise Price and any withholding taxes may be paid by delivering (on a form prescribed by the Company) an irrevocable direction to pledge all or part of the Common Shares being purchased under the Plan to a securities broker or lender approved by the Company, as security for a loan, and to deliver all or part of the loan proceeds necessary to cover the Exercise Price to the Company.

6.4 PROMISSORY NOTE. To the extent that this Section 6.4 is applicable, all or any part of the Exercise Price and any withholding taxes may be paid by delivering (on a form prescribed by the Company) a full-recourse promissory note, which may include a security interest in the shares issued under the Option. However, the par value of the Common Shares being purchased under the Plan, if newly issued, shall be paid in cash or cash equivalents.

6.5 OTHER FORMS OF PAYMENT. To the extent that this Section 6.5 is applicable, all or any part of the Exercise Price and any withholding taxes may be paid in any other form that is consistent with applicable laws, regulations and rules.

**ARTICLE 7.**

7.1 ACCELERATED EXERCISABILITY. All NSOs granted to an Outside Director under this Article 7 shall become exercisable in full in the event of:

(a) the termination of such Outside Director's service because of death, total and permanent disability or retirement at or after age 70; or

(b) a Change in Control (as defined in Section 14.4 below) with respect to the Company, except as provided in the next following sentence.

7.2 EXERCISE PRICE. The Exercise Price under all NSOs granted to an Outside Director under this Article 7 shall be equal to 100% of the Fair Market Value of a Common Share on the date of grant, payable in one of the forms described in Sections 6.1, 6.2, 6.3 and 6.4.

7.3 TERM. Unless otherwise provided in the Stock Option Agreement, all NSOs granted to an Outside Director under this Article 7 shall terminate on the earliest of (a) the 10th anniversary of the date of grant, or (b) the date 12 months after the termination of such Outside Director's service as a Director.

7.4 AFFILIATES OF OUTSIDE DIRECTORS. The Committee may provide that the NSOs that otherwise would be granted to an Outside Director under this Article 7 shall instead be granted to an affiliate of such Outside Director. Such affiliate shall then be deemed to be an Outside Director for purposes of the Plan, including that the service-related vesting and termination provisions pertaining to the NSOs shall be applied with regard to the service of the Outside Director.

**ARTICLE 8. RESTRICTED SHARES.**

8.1 RESTRICTED STOCK AGREEMENT. Each grant of Restricted Shares of Common Stock under the Plan shall be evidenced by a Restricted Stock Agreement between the recipient and the Company. Such Restricted Shares shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan. The provisions of the various Restricted Stock Agreements entered into under the Plan need not be identical.

8.2 PAYMENT FOR AWARDS. Subject to the following sentence, Restricted Shares may be sold or awarded under the Plan for such consideration as the Board or the Committee may determine, including (without limitation) cash, cash equivalents, full-recourse promissory notes, past services and future services. To the extent that an Award consists of newly issued Restricted Shares, the Award recipient shall furnish consideration with a value not less than the par value of such Restricted Shares in the form of cash, cash equivalents or past services rendered to the Company (or a Parent or Subsidiary), as the Committee may determine.

8.3 VESTING CONDITIONS. Unless otherwise approved by the Board of Directors and provided in the Restricted Stock Agreement, the Restricted Shares shall vest pro rata over a period of four (4) years, with 25% of the Option vesting on each of the first, second, third and fourth anniversaries of the date of grant. A Restricted Stock Agreement may provide for accelerated vesting in the event of the Participant's death, disability or retirement or other events. All Restricted Shares shall become vested in the event that a Change in Control (as defined in Section 14.4) occurs with respect to the Company, except as provided in the next following sentence.

8.4 VOTING AND DIVIDEND RIGHTS. The holders of Restricted Shares awarded under the Plan shall have the same voting, dividend and other rights as the Company's other stockholders.

**ARTICLE 9. PROTECTION AGAINST DILUTION.**

9.1 ADJUSTMENTS. In the event of a subdivision of the outstanding Common Shares, a declaration of a dividend payable in Common Shares, a declaration of a dividend payable in a form other than Common Shares in an amount that has a material effect on the price of Common Shares, a combination or consolidation of the outstanding Common Shares (by reclassification or otherwise) into a lesser number of Common Shares, a recapitalization, a spin-off or a similar occurrence, the Board of the Committee shall make such adjustments as it, in its sole discretion, deems appropriate in one or more of (a) the number of Options and Restricted Shares available for future Awards under Article 3, (b) the limitations set forth in Section 5.2, (c) the number of Common Shares covered by each outstanding Option or (d) the Exercise Price under each outstanding Option. Except as provided in this Article 9, a Participant shall have no rights by reason of any issue by the Company of stock of any class or securities convertible into stock of any class, any subdivision or consolidation of shares of stock of any class, the payment of any stock dividend or any other increase or decrease in the number of shares of stock of any class.

9.2 DISSOLUTION OR LIQUIDATION. To the extent not previously exercised, Options shall terminate immediately prior to the dissolution or liquidation of the Company.

9.3 REORGANIZATIONS. In the event that the Company is a party to a merger or other reorganization, outstanding Options and Restricted Shares shall be subject to the agreement of merger or reorganization. Such agreement may, but is not required to, provide for one or more of the following: (a) the continuation of the outstanding Awards by the Company, if the Company is a surviving corporation, (b) the assumption of the outstanding Awards by the surviving corporation or its parent or subsidiary, (c) the substitution by the surviving corporation or its parent or subsidiary of its own awards for the outstanding Awards, (d) full exercisability or vesting and accelerated expiration of the outstanding Awards or (e) settlement of the full value of the outstanding Awards in cash or cash equivalents followed by cancellation of such Awards.

**ARTICLE 10. AWARDS UNDER OTHER PLANS.**

The Company may grant awards under other plans or programs. Such awards may be settled in the form of Common Shares issued under this Plan. Such Common Shares shall be treated for all purposes under the Plan like Restricted Shares and shall, when issued, reduce the number of Common Shares available under Article 3.

**ARTICLE 11. LIMITATION ON RIGHTS.**

11.1 RETENTION RIGHTS. Neither the Plan nor any Award granted under the Plan shall be deemed to give any individual a right to remain an Employee, Outside Director or Consultant. The Company and its Parents, Subsidiaries and Affiliates reserve the right to terminate the service of any Employee, Outside Director or Consultant at any time, with or without cause, subject to applicable laws, the Company's certificate of incorporation and by-laws and a written employment agreement (if any).

11.2 STOCKHOLDERS' RIGHTS. A Participant shall have no dividend rights, voting rights or other rights as a stockholder with respect to any Common Shares covered by his or her Award prior to the time when a stock certificate for such Common Shares is issued or, in the case of an Option, the time when he or she becomes entitled to receive such Common Shares by filing a notice of exercise and paying the Exercise Price. No adjustment shall be made for cash dividends or other rights for which the record date is prior to such time, except as expressly provided in the Plan.

11.3 REGULATORY REQUIREMENTS. Any other provision of the Plan notwithstanding, the obligation of the Company to issue Common Shares under the Plan shall be subject to all applicable laws, rules and regulations and such approval by any regulatory body as may be required. The Company reserves the right to restrict, in whole or in part, the delivery of Common Shares pursuant to any Award prior to the satisfaction of all legal requirements relating to the issuance of such Common Shares, to their registration, qualification or listing or to an exemption from registration, qualification or listing.

**ARTICLE 12. WITHHOLDING TAXES.**

12.1 GENERAL. To the extent required by applicable federal, state, local or foreign law, a Participant or his or her successor shall make arrangements satisfactory to the Company for the satisfaction of any withholding tax obligations that arise in connection with the Plan. The Company shall not be required to issue any Common Shares or make any cash payment under the Plan until such obligations are satisfied.

**ARTICLE 13. FUTURE OF THE PLAN.**

13.1 TERM OF THE PLAN. The Plan, as set forth herein, shall become effective upon approval of the Plan by the Company's stockholders (expected to be obtained on or about December 10, 2020). The Plan shall remain in effect until December 10, 2030, unless earlier terminated under Section 13.2, except that no ISOs shall be granted on or after the 10th anniversary of the later of (a) the date when the Board adopted the Plan or (b) the date when the Board adopted the most recent increase in the number of Common Shares available under Article 3 which was approved by the Company's stockholders.

13.2 AMENDMENT OR TERMINATION. The Board may, at any time and for any reason, amend or terminate the Plan. An amendment of the Plan shall be subject to the approval of the Company's stockholders only to the extent required by applicable laws, regulations or rules. No Awards shall be granted under the Plan after the termination thereof. The termination of the Plan, or any amendment thereof, shall not affect any Award previously granted under the Plan.

**ARTICLE 14. DEFINITIONS.**

14.1 "AFFILIATE" means any entity other than a Subsidiary, if the Company and/or one or more Subsidiaries own not less than 50% of such entity.

14.2 "AWARD" means any award of an Option or a Restricted Share under the Plan.

14.3 "BOARD" means the Company's Board of Directors, as constituted from time to time.

14.4 "CHANGE IN CONTROL" shall mean:

(a) the consummation of a merger or consolidation of the Company with or into another entity or any other corporate reorganization, if more than 50% of the combined voting power of the continuing or surviving entity's securities outstanding immediately after such merger, consolidation or other reorganization is owned by persons who were not stockholders of the Company immediately prior to such merger, consolidation or other reorganization;

(b) the sale, transfer or other disposition of all or substantially all of the Company's assets;

(c) a change in the identity of a majority of the members of the Company's Board of Directors that becomes effective on a single date (provided, however, that the appointments of new directors upon the deaths or resignations of directors by the remaining directors then in office shall not constitute a change in identity with respect to such departed director); or

(d) any transaction as a result of which any person is the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing at least 50% of the total voting power represented by the Company's then outstanding voting securities. For purposes of this Subsection (d), the term "person" shall have the same meaning as when used in sections 13(d) and 14(d) of the Exchange Act but shall exclude (i) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or of a Parent or Subsidiary and (ii) a corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of the common stock of the Company. A transaction shall not constitute a Change in Control if its sole purpose is to change the state of the Company's incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

14.5 "CODE" means the Internal Revenue Code of 1986, as amended.

14.6 "COMMITTEE" means a committee of the Board, as described in Article 2.

14.7 "COMMON SHARE" means one share of the common stock of the Company.

14.8 "COMPANY" means Biomerica, Inc., a Delaware corporation.

14.9 "CONSULTANT" means a consultant or adviser who provides bona fide services to the Company, a Parent, a Subsidiary or an Affiliate as an independent contractor. Service as a Consultant shall be considered employment for all purposes of the Plan, except as provided in Section 4.2.

14.10 "EMPLOYEE" means an employee of the Company, a Parent, a Subsidiary or an Affiliate.

14.11 "EXCHANGE ACT" means the Securities Exchange Act of 1934, as amended.

14.12 "EXERCISE PRICE" means the amount for which one Common Share may be purchased upon exercise of such Option, as specified in the applicable Stock Option Agreement.

14.13 "FAIR MARKET VALUE" means the market price of Common Shares, determined by the Board or the Committee in good faith on such basis as it deems appropriate. Whenever possible, the determination of Fair Market Value by the Committee shall be based on the prices reported in The Wall Street Journal. Such determination shall be conclusive and binding on all persons.

14.14 "ISO" means an incentive stock option described in section 422(b) of the Code.

14.15 "NSO" means a stock option not described in sections 422 of the Code.

14.16 "OPTION" means an ISO or NSO granted under the Plan and entitling the holder to purchase Common Shares.

14.17 "OPTIONEE" means an individual or estate who holds an Option.

14.18 "OUTSIDE DIRECTOR" shall mean a member of the Board who is not an Employee. Service as an Outside Director shall be considered employment for all purposes of the Plan, except as provided in Section 4.2.

14.19 "PARENT" means any corporation (other than the Company) in an unbroken chain of corporations ending with the Company, if each of the corporations other than the Company owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Parent on a date after the adoption of the Plan shall be considered a Parent commencing as of such date.

14.20 "PARTICIPANT" means an individual or estate who holds an Award.

14.21 "PLAN" means this Biomerica, Inc. 2020 Stock Incentive Plan, as amended from time to time.

14.22 "RESTRICTED SHARE" means a Common Share awarded under the Plan.

14.23 "RESTRICTED STOCK AGREEMENT" means the agreement between the Company and the recipient of a Restricted Share that contains the terms, conditions and restrictions pertaining to such Restricted Share.

14.24 "STOCK OPTION AGREEMENT" means the agreement between the Company and an Optionee that contains the terms, conditions and restrictions pertaining to his or her Option.

14.25 "SUBSIDIARY" means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Subsidiary on a date after the adoption of the Plan shall be considered a Subsidiary commencing as of such date.

**ARTICLE 15. EXECUTION.**

To record the adoption of the Plan by the Board, the Company has caused its duly authorized officer to execute this document in the name of the Company.

BIOMERICA, INC.

By: /s/ Janet Moore

Name: Janet Moore

Title: Secretary

Date approved by Board of Directors: February 7, 2020

Date Approved by Shareholders: \_\_\_\_\_

**CONSENT OF INDEPENDENT  
REGISTERED PUBLIC ACCOUNTING FIRM**

Biomerica, Inc. and Subsidiaries  
Irvine, California

We hereby consent to the incorporation by reference in, the previously filed Registration Statements on Form S-8 (Nos. 333-33494, 333-179443, 333-204410 and 333-224836) and Form S-3 (No. 333-239980) of Biomerica, Inc. and Subsidiaries, of our report dated August 31, 2020, relating to the consolidated financial statements as of May 31, 2020 and 2019 and for the years ended May 31, 2020 and 2019, which appears in this Form 10-K.

/s/ PKF, LLP

PKF, LLP

San Diego, CA  
August 31, 2020

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Zackary S. Irani, certify that:

1. I have reviewed this Annual Report on Form 10-K of Biomerica, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of our internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or other persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Zackary S. Irani  
Zackary S. Irani  
Chief Executive Officer

Date: August 31, 2020

**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Janet Moore, certify that:

1. I have reviewed this Annual Report on Form 10-K of Biomerica, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of our internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or other persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Janet Moore  
Janet Moore  
Chief Financial Officer

Date: August 31, 2020

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Biomerica, Inc. (the "Company") on Form 10-K for the year ended May 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Zackary Irani, Chief Executive Officer of the Company, certify, to the best of my knowledge, Pursuant to Exchange Act Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002,

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

/s/ Zackary S. Irani  
Zackary S. Irani  
Chief Executive Officer

Date: August 31, 2020

**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Biomerica, Inc. (the "Company") on Form 10-K for the year ended May 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Janet Moore, Chief Financial Officer of the Company, certify, to the best of my knowledge, Pursuant to Exchange Act Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002,

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

/s/ Janet Moore  
Janet Moore  
Chief Financial Officer

Date: August 31, 2020