

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, 2022 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

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

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, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Smaller Reporting Company

Emerging Growth Company

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in 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 11,486,578 shares held by non-affiliates and the closing price of \$4.85 per share for Common Stock as of November 30, 2021): \$55,709,903.

The outstanding number of shares of common stock, par value \$0.08, as of August 29, 2022 was 13,391,901.

DOCUMENTS INCORPORATED BY REFERENCE: Portions of the registrant's definitive Proxy Statement for the 2022 annual meeting of stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III, Items 10-14 of this Form 10-K. Except for the portions of the Proxy Statement specifically incorporated by reference in this Form 10-K, the Proxy Statement shall not be deemed to be filed as part hereof.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Except for historical financial information contained herein, the matters discussed in this Form 10-K may be considered forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and subject to the safe harbor created by the Securities Litigation Reform Act of 1995. Such statements include declarations regarding our intent, belief, or current expectations, and those of our management. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other comparable terminology. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve a number of risks, uncertainties and other factors, some of which are beyond our control. Actual results could differ materially from those indicated by such forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, but are not limited to, those risks and uncertainties identified under “Risk Factors,” in this Form 10-K and the other risks detailed from time-to-time in our reports and registration statements filed with the Securities and Exchange Commission, or SEC. Except as required by law, we undertake no obligation to revise or update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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. Our products are designed to enhance the health and well-being of people, while reducing total healthcare costs.

Our primary focus is the research, development, commercialization and in certain cases regulatory approval, of 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. Our InFoods® IBS product uses a simple blood sample and is designed to identify patient-specific foods that, when removed from the diet, may alleviate Irritable Bowel Syndrome ("IBS") symptoms such as pain, bloating, diarrhea and constipation. Instead of broad and difficult to manage dietary restrictions, the InFoods® IBS product works by identifying a patient's above normal immunoreactivity to specific foods. A food identified as positive, and causing an abnormal immune response in the patient is simply removed from the diet to help alleviate IBS symptoms.

During fiscal 2022, we completed an endpoint determination clinical trial on our InFoods® IBS product. This trial was conducted at 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, the University of Michigan and other institutions. This trial monitored IBS patients over an 8-week period to determine the efficacy of our InFoods® IBS product to improve the patients' IBS symptoms or endpoints. The top-line trial results were reported in February 2022. Multiple endpoints demonstrated statistically significant improvements, indicating that the elimination of specific foods may meaningfully reduce the symptoms of IBS in all patient subtypes (including patients with IBS-Constipation, IBS-Diarrhea & IBS-Mixed). The greatest clinical improvements, including but not limited to abdominal pain and bloating, were seen in patients diagnosed with IBS-Mixed and IBS-Constipation, in the top line data. The purpose of the endpoint study was to determine the primary symptom endpoint, or endpoints to be used in a final pivotal trial that will be conducted to attain the validation data needed to apply for U.S. Food and Drug Administration ("FDA") clearance for the product. We are now in the process of reviewing the complete dataset and selecting the target endpoint(s) to be used in the pivotal trial. We are also writing the protocols for this trial and expect to present these protocols to the FDA during fiscal 2023, with the intention of beginning the trial by the end of fiscal 2023, or May 31, 2023. The trial is expected to include the large medical institution participants that conducted the endpoint trial, in addition to other new institutions and a Clinical Research Organization.

Following the successful completion and positive results from the Company's InFoods® IBS clinical trial we've seen significant interest from Gastroenterology ("GI") physicians who would like to provide the InFoods® IBS Product to for their patients immediately. Therefore, while we are proceeding with the work needed to seek FDA clearance for this product, we also are currently preparing to launch the InFoods® IBS product through a CLIA-certified, high-complexity laboratory facility and offering the product as a laboratory developed test ("LDT"). Our expectation is that we will begin to generate revenues from this product by the end of December 31, 2022. In preparation for the launch of this LDT, we are in negotiations with large physician groups that would like to offer the LDT to their IBS patients.

We are also beginning the work of selecting and validating at least one new disease (such as ulcerative colitis or migraines), where there is evidence that certain foods can trigger or contribute to the symptoms found in these indications. We expect any new disease we target will follow a similar development pathway as InFoods IBS in simultaneously seeking FDA clearance of the product while also launching the product as an LDT.

We will also continue to evaluate partnership/licensing opportunities, as they arise, with U.S. and multinational companies that could help us commercialize, or accelerate revenue growth of, the InFoods products in the United States and overseas.

Our existing medical diagnostic products are sold worldwide primarily in two markets: 1) clinical laboratories and 2) point-of-care (physicians' offices and over-the-counter drugstores like Walmart and Walgreens). The diagnostic test kits are used to analyze blood, urine, nasal or fecal specimens from patients in the diagnosis of various diseases, food intolerances 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.

During fiscal 2022, we finalized development of our H. Pylori diagnostic test that indicates if a patient is infected with the H. Pylori bacteria. H. Pylori infection is extremely common, and if left untreated, can lead to ulcers and possibly stomach cancers. During our fourth quarter of fiscal 2022, we applied for FDA clearance of this product through a 510(k) premarket submission. We have been in communications with the FDA answering certain follow-up questions and providing additional data as requested. We are currently awaiting FDA clearance of the product. Once cleared, we will begin marketing the product in the U.S. market.

Following fiscal year-end, we announced that Walmart has begun selling our Aware[®] Breast Self Exam product through their on-line retailing platform, Walmart.com. We are also in final discussions with Walmart to offer this product in their U.S. based retail stores.

We have added new employees in our sales and marketing department in order to increase sales of existing products during fiscal 2022. Through these efforts, our EZ Detect colon disease home screening test and our Aware[®] Breast Self Exam product are seeing an increased interest from retailers such as Walmart, distributors, and screening programs in other countries.

Due to the global 2019 SARS-CoV-2 novel coronavirus pandemic, in March 2020 we began developing COVID-19 products to indicate if a person has been infected by COVID-19, or is currently infected. While we offer a COVID-19 antibody diagnostic test to determine if a person has previously been infected by the COVID-19 virus, all of our COVID-19 revenues in fiscal 2022 have come from international sales of our COVID-19 antigen tests that use a patient's nasal fluid sample to detect if the patient is currently infected with the virus.

While sales continue to occur in our COVID-19 products, the majority of our research and development efforts are focused on development and commercialization of non-COVID related products such as our H. Pylori product, and our InFoods[®] IBS product.

The other existing products that contributed to our 2022 revenues are primarily focused on gastrointestinal diseases, food intolerances, and certain esoteric tests. These diagnostic test products utilize immunoassay technology. Most of 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 United States 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 also has 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 require 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.

We expend 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 technical 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.

Biomerica maintains its headquarters in Irvine, California, where it houses administration, finance, regulatory compliance, product development, sales and marketing, customer services and its primary manufacturing operations. Biomerica maintains manufacturing and assembly operations in Mexicali, Mexico, in order to reduce the cost of manufacturing and compete more effectively worldwide. Biomerica also has a legal entity in Europe, BioEurope GmbH, for the purpose of selling certain products internationally.

Additional information about Biomerica is available on our website at 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.

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

During most of the fiscal year, in addition to our focus on development our InFoods® IBS product, we also focused a portion of our Research and Development (“R&D”) resources on developing a H. Pylori diagnostic test. Our research and development spending are due to our focus on these tests and outside clinical studies intended to demonstrate the feasibility of FDA clearance for such tests. We also utilize 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 we may wish to develop and commercialize. Research and development expenses include the costs of materials, supplies, personnel, consultants, 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, 2022 and 2021, aggregated to approximately \$1,812,000, and \$2,194,000, respectively. As Biomerica moves forward with development, validation and commercialization of additional key products that address diseases with large market opportunities, research and development expenses are expected to increase during upcoming quarters.

We’ve 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 patient’s diet, may alleviate or improve their symptoms of IBS. The United States Patent and Trademark Office (“USPTO”) has issued the Company two patents with broad claims that protect this InFoods® IBS product. Patents have also been issued in the countries of Australia, Japan, Korea, Mexico, and Singapore. Additional patent application pertaining to the InFoods® IBS product have been filed in the United States and in other countries. We are also developing and have filed patents for products that target other diseases utilizing the InFoods® technology platform which include: Functional Dyspepsia, Crohn’s disease, Ulcerative Colitis, Gastroesophageal Reflux disease (“GERD”), Migraine Headaches, Depression and Osteoarthritis. Our first patent to be allowed for a disease/illness other than IBS was allowed in Japan in August 2021. This patent covers the use of our InFoods® technology to diagnose and treat persons suffering from depression. We are planning to pursue FDA Clearance through a De Novo submission with the FDA rather than a Premarket Approval Application (“PMA”) or 510(k) for the InFoods® IBS product.

During the fourth quarter of fiscal 2022, we also submitted our proprietary H. Pylori test to the FDA for clearance through a 510(k) submission. The clinical studies for our H. Pylori were conducted at the University of Southern California (“USC”), a European University and several other U.S. locations. Biomerica’s test is designed to provide highly accurate sensitivity and specificity for H. pylori testing and for monitoring of treatment.

MARKETS AND METHODS OF DISTRIBUTION

Biomerica has approximately 250 current customers for its diagnostic business, of which approximately 80 are foreign distributors, 10 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 over 20 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 United States and we expect that she will continue to help Biomerica add new distributors for existing products and add new product-lines for future distribution by us.

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).

Due to the Coronavirus global pandemic, our operations have been negatively impacted. We have 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 our manufacturing or distribution facilities or of the facilities of our suppliers, partners and customers, travel, shipping and logistical disruptions, government responses of all types, international business risks in countries where we make and/or sell our 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 ongoing pandemic related disruptions can materially negatively impact our operations and financial performance and may continue to have significant material negative impacts on us.

Our net sales were approximately \$18,871,000 for fiscal 2022 compared to \$7,199,000 for fiscal 2021. For the fiscal years ended May 31, 2022 and 2021, the Company had two distributors, which accounted for a total of 65% and 60% of our net sales, respectively. Of this, for the fiscal years ended May 31, 2022 and 2021, the largest of the distributors mentioned above accounted for 55% and 33%, respectively, of net sales.

Total gross receivables at May 31, 2022 and 2021 were approximately \$927,000 and \$2,292,000, respectively. As of May 31, 2022 and 2021, the Company had one distributor and two distributors, respectively, which accounted for a total of 50% and 73%, respectively, of gross accounts receivable. Of the 50% as of May 31, 2022, 50% was owed by a distributor in Asia.

BACKLOG

On May 31, 2022 and 2021, Biomerica had a backlog of unshipped orders of approximately \$754,000 and \$85,000, respectively. On May 31, 2022, this consisted primarily of orders to a distributor in Asia.

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 we may encounter difficulty in the future obtaining key raw materials for its manufacturing processes or that such materials may be exceedingly costly. For the fiscal years ended May 31, 2022 and 2021, the Company had one vendor, which accounted for 84% and 58%, respectively 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 mandated or recommended shut-downs, restrictions and constraints 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.

INFLATION

Due to the global and domestic supply chain disruptions, and overall inflationary pressures in the economy, we have experienced material increases in the cost of our raw materials and in our operating and labor costs. While we have attempted to respond by increasing the selling price of our own products, the gross margins on our products sold have been negatively impacted.

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 for most of the product categories in which we compete. However, we do have certain proprietary products, such as our EZ Detect colon disease home test, the Aware Breast Self Exam product and our InFoods[®] IBS that do not have significant competition from tests offered by competitors, and that do not have the features and benefits of our tests.

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. However, during the past 18 months, we have expanded our sales and marketing capability, through marketing and strategic cooperation with larger companies and distributors and by hiring new employees with 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 medical devices and medical devices. As a result, we are considered to be an in vitro diagnostic medical devices 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, as well as European Government agencies. 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 in vitro diagnostic medical devices and 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. Our 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. Our current license is valid until November 19, 2022. 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. We comply with In Vitro Diagnostic Medical Devices Directive (“IVDD”) 98/79/EC and Medical Devices Regulation 2017/745 (“MDR”). We also comply with ISO 13485:2016 Medical Devices Quality Management Systems - Requirements for Regulatory Purposes.

At present, outside the EU the regulatory international review process varies from country to country. We work with 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 these products to be manufactured in accordance with the FDA’s current Good Manufacturing Practice (cGMP) 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 post -market surveillance. The last FDA announced inspection was in November 2019 and no observations were noted. We believe that all Biomerica products sold in the United States comply with the FDA and state regulations.

We are an FDA regulated and ISO 13485:2016 certified In Vitro Diagnostic 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, ISO 13485:2016, Medical Devices Quality Management Systems - Requirements for Regulatory Purposes, In Vitro Diagnostic Medical Devices Directive 98/79/EC & and Medical Device Regulation 2017/745, Guidelines related to Medical Devices Directive/Regulation and Guidance on CE Marking, etc. Biomerica involves 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 In Vitro Diagnostic Medical Device Regulation (“IVDR”) 2017/746 was effective on May 26, 2022. Manufacturers need 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. Since August 19, 2021, our Notified Body is officially designated under the IVDR and listed in the European Commission NANDO database. We are working closely with our Notified Body to update our technical documentation to comply with these new and more stringent IVDR requirements.

Per IVDR 2017/746 Amendment 2021/0323 (COD), devices with a CE certificate that was issued in accordance with IVDD may be placed on the market or put into service until May 26, 2025.

Exceptional Renewal of CE Certificate for IVDD Quality System was granted to Biomerica. Biomerica received an extended CE Certificate on May 24, 2022, which remains effective until May 26, 2025. Biomerica has until May 26, 2025, to update the technical documentation and processes to meet the new, more stringent regulatory requirements of IVDR 2017/746.

Per IVDR 2017/746 Amendment 2021/0323 (COD), devices without a CE certificate that was issued in accordance with IVDD, for which a declaration of conformity was drawn up prior to May 26, 2022, per IVDD and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a Notified Body, may be placed on the market or put into service until the following dates. Biomerica also has until the following dates to update the technical documentation and processes to meet the new, more stringent regulatory requirements of IVDR 2017/746:

- (1) May 26, 2025, for class D devices;
- (2) May 26, 2026, for class C devices;
- (3) May 26, 2027, for class B devices; and
- (4) May 26, 2027, for class A devices placed on the market in sterile condition.

SEASONALITY OF BUSINESS

Our businesses 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 our last two fiscal years:

	For the year ended May 31,			
	2022		2021	
Asia	\$ 13,375,000	71%	\$ 1,908,000	26%
Europe	4,339,000	23%	4,301,000	60%
North America	997,000	5%	548,000	8%
South America	90,000	1%	250,000	3%
Middle East	70,000	0%	192,000	3%
Total	\$ 18,871,000	100%	\$ 7,199,000	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, embargos, trade wars, import/export 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, and other disease outbreaks that cause 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 our ability 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 sales of our diagnostic products are made primarily through a network of approximately 80 independent distributors in approximately 30 countries.

The COVID-19 related factors mentioned above and in "Risk Factors" negatively impacted domestic and international sales of our non-COVID-19 products during fiscal 2022 and may continue to negatively impact our 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, trade secrets, 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.

We have a royalty agreement in which we obtained rights to manufacture and market an ACTH test (used to detect chronic metabolic conditions). Royalty expense of approximately \$19,000 and \$11,000, respectively, is included in cost of sales for this agreement for the fiscal years ended May 31, 2022 and 2021. Sales of products manufactured under this agreement are not material to total sales for the fiscal years ended May 31, 2022 and 2021, respectively. We may license other products or technology in the future as it deems necessary or opportunistic for conducting business.

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 may use to produce a more accurate 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. Collaboration efforts on a CRISPR product that may be commercialized using this technology continues, however, there are no imminent plans to launch a product from this collaboration.

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 us. 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 U.S. Patent and Trademark Office ("USPTO"). 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 2001, renewed in 2011 and 2021. On January 11, 2020, the USPTO renewed our "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 United States. Effective copyright, trademark and trade secret protection may not be available in such jurisdictions.

PATENTS AND INFOODS TECHNOLOGY

We have filed over 100 international and Patent Corporation Treaty patents and have over 10 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, allowed or issued pertain to the InFoods® technology platform.

Our most important family of patent applications pertains to our InFoods® technology platform, which is a new method of diagnosing and treating symptoms of many different inflammatory diseases. Our first planned product launch using this technology is the InFoods® IBS product which is designed to diagnose and treat IBS. 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 an IBS patient's diet, can alleviate or reduce the individual's IBS symptoms, including, but not limited to, constipation, diarrhea, bloating, cramping, 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® 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, osteoarthritis, psoriasis, migraine headaches and depression. These applications include the use of this technology in both humans and animals. The first InFoods® patents filed by us pertained to IBS. 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, we received our first patent from the Korean Intellectual Property Office, covering our InFoods® IBS product. Since then we have been granted an additional 11 patents; 3 in Japan, 2 in the United States, 2 in Korea, 1 in Singapore, 1 in Mexico, 1 in Canada, and 1 in Australia. Additionally, we have filed for over 100 international and USPTO patents.

We believe the claims in these issued InFoods® IBS patents and claims in our pending patents that protect the use of the InFoods® technology to diagnose and treat various 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, we have 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. We anticipate that we will license or purchase the rights to other products or technologies in the future.

We recently completed an endpoint determination clinical trial on our InFoods® IBS product. Our business model for this product includes the possible out-licensing of this product and the related patents to a large international life sciences or technology company that would commercialize the product or assist us with the commercialization.

EMPLOYEES

As of May 31, 2022 and 2021, we employed a total of 64 and 67 employees, respectively, in the United States, Mexico, and Germany, of which 64 and 67 were full-time employees, respectively. Various employees listed in the production department also perform research and development duties as a routine function of their job. We occasionally employ temporary employees when needed.

The following is a breakdown of employees by departments:

	May 31,	
	2022	2021
Administrative	8	10
Research & Development	8	8
Sales & Marketing	6	5
Production & Operations	42	44
Total	64	67

We also engage the services of many outside Ph.D.'s, M.D.'s and other types of industry expert consultants and organizations 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 experts 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 ongoing outbreaks of illness or other health issue, such as the recent COVID-19 Coronavirus outbreak. The outbreak of the COVID-19 virus caused various governments, including the United States, to implement quarantines, various restrictions on travel and 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 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 and 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.

We have a history of operating losses.

We have historically incurred net losses. There can be no assurance that we will generate net profits in future periods. Further, there can be no assurance that we will be cash flow positive in future periods. In the event that we fail to achieve profitability in future periods, the value of our common stock may decline. In addition, if we are unable to achieve or maintain positive cash flows, we would be required to seek additional funding, which may not be available on favorable terms, if at all.

Our operating results may fluctuate adversely as a result of many factors that are outside our control, which may negatively impact our stock price.

Our operating results are dependent upon many factors that are substantially outside of our control that could materially and adversely affect our business, results of operations and financial condition. 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.

Fluctuations in our operating results, for any reason, could cause operating losses as a result of significant fixed expenses.

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.

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, or selling products at lower prices.

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. This includes the possibility and risk that the Company's products do not meet the new EU IVDR testing and documentation requirements in the future as described in the above "Research and Development" section of this document.

Significant government regulation exists in countries in which we conduct business. A large part of the Company's sales is 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. In addition, the Company warehouses a significant amount of its inventory at the Mexico facility. 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.

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.

Our net sales were approximately \$18,871,000 for fiscal 2022 compared to \$7,199,000 for fiscal 2021. For the fiscal years ended May 31, 2022 and 2021, the Company had two distributors, which accounted for a total of 65% and 60% of our net sales, respectively. Of this, for the fiscal years ended May 31, 2022 and 2021, the largest of the distributors mentioned above accounted for 55% and 33%, respectively, of net sales.

Total gross receivables on May 31, 2022 and 2021 were approximately \$927,000 and \$2,292,000, respectively. As of May 31, 2022 and 2021, the Company had one distributor and two distributors, respectively, which accounted for a total of 50% and 73%, respectively, of gross accounts receivable. Of the 50% as of May 31, 2022, 50% was owed by a distributor in Asia. 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 United States which can be difficult to collect.

We extend credit to many of our customers including those outside of the United States. 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 United States. Our inability to collect on receivables from customers, in particular those outside of the United States 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 into larger facilities, expanding the scope of operating and financial systems and the geographical area of our operations, including further expansion outside the United States, 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 core 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. Any and all of these potential growth and expansion strategies and events could impose material risks and cause the Company to incur adverse operating and financial results.

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, result in significant costs, and materially adversely affect our operating results.

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 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. In addition, the defense of such claims could result in significant costs and divert the attention of our management and other key employees.

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.

As a company focused on research and development of new products that do not yet generate revenues, 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 future costs could be much higher than anticipated and current operations are unlikely 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 consumers, 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 in the medical community for any of our new products is unpredictable at this time. In addition, the Company will need to spend considerable funds in order to introduce new 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 our products or whose products are more accurate than our products. We can provide no assurances that consumers and 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, larger, more established marketing, sales, distribution and service organizations; more established relationships with healthcare professionals; and greater experience in conducting research and development, manufacturing, clinical trials, and obtaining regulatory approval for products. 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 United States, 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, embargos, trade wars or modifications to existing legislation, such as U.S. tax policy, or entirely new legislation, such as the Affordable Healthcare Act in the United States. We cannot predict the many ways that healthcare reform in the United States and internationally, and changing trade legislation and policies could adversely 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 United States, 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 United States 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 United States 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, governmental restrictions or stay-at-home orders in response to natural disasters (including pandemics), 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 or engage third-party manufacturers to meet these demands. These capital resources could involve the cost of new machinery or even the cost of new manufacturing facilities. In addition, engaging third-party manufacturers would increase manufacturing costs and reduce margins. This would increase our capital costs or third-party expenses, which could adversely affect our earnings and cash resources. If we are unable to develop or obtain necessary manufacturing capabilities in a timely manner or to engage third-party manufacturers to meet demand, 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 product recalls, claims of liability and harm to patients or users of our products, or 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 require a product recall or otherwise have a substantial impact on our revenues and financial performance. Any substantial underinsured loss resulting from such a claim or defect 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, analyze and interpret 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. Cyber security is a great and growing risk to operating companies. Cyber-attacks may result in loss of vital Company documentation and data, or confidential third-party documents held by the Company, that are necessary for the Company to operate. 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 and material adverse financial costs to the Company. 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.

The Company's lease obligations and growth expectations could create financial and operating risks.

Given the recent growth in the Company's operations, it is uncertain the current leased facilities will be able to accommodate the Company's operations in the future. As such, the Company may need to move to new facilities that would require the Company to seek to sublease its current facilities for the remainder of the lease(s) at a potential discount to the existing monthly lease obligation cost. Alternatively, the Company could be required to move a portion of its operations to a new facility which could be disruptive both short term and long term to the Company's operations and create additional fixed costs.

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 United States 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 by the Company 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 "shelf" registration statement on Form S-3. The registration statement registers common shares that may be issued by the Company in a maximum aggregate amount of up to \$90,000,000. Shares of our common stock may be sold from time to time under this registration statement for up to three years from the filing date. On January 22, 2021, we filed a prospectus supplement for the sale of up to \$15,000,000 of shares of our common stock in an at-the-market offering under the shelf registration statement, of which approximately \$9,600,000, remains available for sale under the prospectus supplement.

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, Financial Industry Regulation Authority 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;
- the Company reporting material weakness in our internal control;
- changes in stock market analyst recommendations regarding our common stock;
- changes in healthcare policy in the United States or other countries;
- lawsuits or liability claims from shareholders or other parties;
- legal disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates, and the results of any proceedings or lawsuits, including patent or shareholder litigation;
- sales of our common stock or other securities by us or our stockholders in the future;
- trading volume of our common stock;
- actual or anticipated variations in quarterly operating results;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- effects of natural or man-made catastrophic events, including widespread public health epidemics like the pandemic related to COVID-19; and
- general stock market conditions and other factors unrelated to our operating performance.

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

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

Although we have Federal income tax net operating loss carryforwards of approximately \$17,116,000 and California state income tax net operating loss carryforwards of approximately \$10,805,000, use of these loss carryforwards will depend on future income in relationship to expirations dates of these carryforwards.

We face risks related to our intellectual property including our patents (IP).

We rely on IP for the current products we sell and for the new products in research, development and in clinical trials. While the Company tries to protect its IP with confidentiality agreements and internal policies, we still face risks that our IP will be stolen or otherwise misappropriated, by parties inside or outside of the United States. Further, we have filed over 100 patents around the world on much of the research and development done by the Company, and the proposed products to come from this research. The vast majority of these filed patents are still under review and have not yet been allowed or issued. We may not be able to attain patent claims that adequately protect the company from competitors developing similar products or copying our products. Finally, there is a great number of issued patents owned by others that pertain to the product categories in which we operate. While we do not know of any patents with claims that we are violating by manufacturing or selling our current products, there is a risk that certain third-party patents will emerge that prohibit us from selling our products or that require us to pay royalty payments. Such third-party claims could have a material negative impact on the Company. Any of these IP related risks could cause material damage to future revenues and to the long-term enterprise values of the Company.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

The Company leases its facilities. On May 31, 2022, 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. On April 9, 2021, the Company exercised its second option to extend its lease for an additional five years. When the Company extended its lease in April 2021, it was also granted an additional five-year lease extension option. The current rent is approximately \$25,000 per month and will increase on September 1, 2022, to \$26,000 per month. The security deposit is approximately \$22,000.

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 located in Mexicali, Mexico. The Company has one 10-year option to renew at the end of the initial lease period. The current rent is approximately \$3,400 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

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 be estimated because of considerable uncertainties that exist. Therefore, it is possible the outcome of such legal proceedings, claims and litigation could have a material negative 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, 2022.

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 26, 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 August 29, 2022, the number of holders of record of Biomerica's common stock was approximately 800, 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.

We did not sell any unregistered equity securities during the year ended May 31, 2022.

We did not purchase any of our shares of common stock or other securities during our fiscal year ended May 31, 2022.

The table below provides information relating to our equity compensation plans as of May 31, 2022:

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 Second Column)
Equity compensation Plans approved by Securities holders	2,321,616	\$3.72	102,801

ITEM 6. RESERVED

Not required.

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

You should read the following discussion and analysis in conjunction with our consolidated financial statements and the accompanying notes thereto included in Part II, Item 8 of this Report. This discussion and analysis contains forward-looking statements that are based on our management's current beliefs and assumptions, which statements are subject to substantial risks and uncertainties. Our actual results may differ materially from those expressed or implied by these forward-looking statements as a result of many factors, including those discussed in "Risk Factors" included in Part I, Item 1A of this Report.

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, nasal 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, development, commercialization and in certain cases regulatory approval, of 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. Our InFoods® IBS product uses a simple blood sample and is designed to identify patient-specific foods that, when removed from the diet, may alleviate Irritable Bowel Syndrome (“IBS”) symptoms such as pain, bloating, diarrhea and constipation. Instead of broad and difficult to manage dietary restrictions, the InFoods® IBS product works by identifying a patient’s above normal immunoreactivity to specific foods. A food identified as positive, and causing an abnormal immune response in the patient is simply removed from the diet to help alleviate IBS symptoms.

During fiscal 2022, we completed an endpoint determination clinical trial on our InFoods® IBS product. This trial was conducted at 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, the University of Michigan, and other institutions. This trial monitored IBS patients over an 8-week period to determine the efficacy of our InFoods® IBS product to improve the patients’ IBS symptoms or endpoints. The top-line trial results were reported in February 2022. Multiple endpoints demonstrated statistically significant improvements, indicating that the elimination of specific foods may meaningfully reduce the symptoms of IBS in all patient subtypes (including patients with IBS-Constipation, IBS-Diarrhea & IBS-Mixed). The greatest clinical improvements, including but not limited to abdominal pain and bloating, were seen in patients diagnosed with IBS-Mixed and IBS-Constipation, in the top line data. The purpose of the endpoint study was to determine the primary symptom endpoint, or endpoints to be used in a final pivotal trial that will be conducted to attain the validation data needed to apply for U.S. Food and Drug Administration (“FDA”) clearance for the product. We are now in the process of reviewing the complete dataset and selecting the target endpoint(s) to be used in the pivotal trial. We are also writing the protocols for this trial and expect to present these protocols to the FDA during fiscal 2023, with the intention of beginning the trial by the end of fiscal 2023, or May 31, 2023. The trial is expected to include the large medical institution participants that conducted the endpoint trial, in addition to other new institutions and a Clinical Research Organization.

Following the successful completion and positive results from the Company’s InFoods® IBS clinical trial we’ve seen significant interest from Gastroenterology (GI) physicians who would like to provide the InFoods® IBS Product to for their patients immediately. Therefore, while we are proceeding with the work needed to seek FDA clearance for this product, we also are currently preparing to launch the InFoods® IBS product through a CLIA-certified, high-complexity laboratory facility and offering the product as a laboratory developed test (LDT). Our expectation is that we will begin to generate revenues from this product by the end of December 31, 2022. In preparation for the launch of this LDT, we are in negotiations with large physician groups that would like to offer the LDT to their IBS patients.

We are also beginning the work of selecting and validating at least one new disease (such as ulcerative colitis or migraines), where there is evidence that certain foods can trigger or contribute to the symptoms found in these indications. We expect any new disease we target will follow a similar development pathway as InFoods IBS in simultaneously seeking FDA clearance of the product while also launching the product as an LDT.

We will also continue to evaluate partnership/licensing opportunities, as they arise, with U.S and multinational companies that could help us commercialize, or accelerate revenue growth of, the InFoods products in the United States and overseas.

Our existing medical diagnostic products are sold worldwide primarily in two markets: 1) clinical laboratories and 2) point-of-care (physicians’ offices and over-the-counter drugstores like Walmart and Walgreens). The diagnostic test kits are used to analyze blood, urine, nasal or fecal specimens from patients in the diagnosis of various diseases, food intolerances 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.

During fiscal 2022, we finalized development of our H. Pylori diagnostic test that indicates if a patient is infected with the H. Pylori bacteria. H. Pylori infection is extremely common, and if left untreated, can lead to ulcers and possibly stomach cancers. During our fourth quarter of fiscal 2022, we applied for FDA clearance of this product through a 510(k) premarket submission. We have been in communications with the FDA answering certain follow-up questions and providing additional data as requested. We are currently awaiting FDA clearance of the product. Once cleared, we will begin marketing the product in the U.S. market.

Following fiscal year-end, we announced that Walmart has begun selling our Aware® Breast Self Exam product through their on-line retailing platform, Walmart.com. We are also in final discussions with Walmart to offer this product in their U.S. based retail stores.

We have added new employees in our sales and marketing department in order to increase sales of existing products during fiscal 2022. Through these efforts, our EZ Detect colon disease home screening test and our Aware[®] Breast Self Exam product are seeing an increased interest from retailers such as Walmart, distributors, and screening programs in other countries

Due to the global 2019 SARS-CoV-2 novel coronavirus pandemic, in March 2020 we began developing COVID-19 products to indicate if a person has been infected by COVID-19 or is currently infected. While we offer a COVID-19 antibody diagnostic test to determine if a person has previously been infected by the COVID-19 virus, all our COVID-19 revenues in fiscal 2022 have come from international sales of our COVID-19 antigen tests that use a patient's nasal fluid sample to detect if the patient is currently infected with the virus.

While sales continue to occur in our COVID-19 products, the majority of our research and development efforts are focused on development and commercialization of non-COVID related products such as our H. Pylori product, and our InFoods[®] IBS product.

The other existing products that contributed to our fiscal 2022 revenues are primarily focused on gastrointestinal diseases, food intolerances, and certain esoteric tests. These diagnostic test products utilize immunoassay technology. Most of 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 United States by the FDA.

RESULTS OF OPERATIONS

Net Sales and Cost of Sales

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

	Twelve Months Ended		Increase (Decrease)	
	May 31,		\$	%
	2022	2021		
Physician's office	\$ 14,259,000	\$ 2,801,000	\$ 11,458,000	409%
Clinical lab	3,064,000	3,077,000	(13,000)	0%
Over-the-counter	1,089,000	766,000	323,000	42%
Contract manufacturing	459,000	555,000	(96,000)	-17%
Total	\$ 18,871,000	\$ 7,199,000	\$ 11,672,000	162%

Our net sales were approximately \$18,871,000 for fiscal 2022 compared to \$7,199,000 for fiscal 2021, an increase of \$11,672,000, or 162%. This increase in annual sales is primarily attributable to sales of COVID-19 tests.

Our cost of sales were approximately \$15,894,000 for fiscal 2022 compared to \$6,833,000 for fiscal 2021, an increase of \$9,061,000, or 133%. This increase was driven by the cost of additional COVID-19 sales. The percentage of cost of sales in fiscal 2022 was 84%, versus 95% in fiscal 2021. In fiscal 2021, we recorded a non-recurring inventory allowance, this increased our cost of sales to 95%. We don't expect to record a significant inventory allowance in future years.

Operating Expenses

The following is a summary of operating expenses:

	Twelve Months Ended				Increase (Decrease)	
	May 31,				\$	%
	2022		2021			
Operating Expense	As a % of Total Revenues	Operating Expense	As a % of Total Revenues			
Selling, General and Administrative Expenses	\$ 5,699,000	30%	\$ 5,672,000	79%	\$ 27,000	0%
Research and Development	\$ 1,812,000	10%	\$ 2,194,000	30%	\$ (382,000)	-17%

Selling, General and Administrative Expenses

Our selling, general and administrative expenses were approximately \$5,699,000 for fiscal 2022 compared to \$5,672,000 for fiscal 2021, an increase of \$27,000, or 0%. The increase was due to an approximate increase of \$400,000 in wages, \$300,000 in consulting fees, and \$200,000 in amortization. Which was primarily offset by a decrease of \$800,000 in bad debt expense related to a specific customer charge in the fiscal 2021.

Research and Development

Our research and development expenses were approximately \$1,812,000 for fiscal 2022 compared to \$2,194,000 for fiscal 2021, a decrease of \$382,000, or 17%, primarily as a result of decreases in costs related to the research, development and validation of COVID-19, IBS and H. Pylori. See "Research and Development" for a more extensive description of the research being conducted.

Interest and Dividend Income

Interest expense decreased in fiscal 2022 to \$0, as compared to \$367 in fiscal 2021. Interest and dividend income for those same years decreased to approximately \$27,000 from \$67,000, respectively. The \$40,000 decrease was due to lower dividend payment from our investment.

LIQUIDITY AND CAPITAL RESOURCES

The following are the principal sources of liquidity:

	May 31,	
	2022	2021
Cash and cash equivalents	\$ 5,917,000	\$ 4,199,000
Working capital including cash and cash equivalents	\$ 7,416,000	\$ 7,931,000

As of May 31, 2022 and 2021, the Company had cash and cash equivalents of approximately \$5,917,000 and \$4,199,000, respectively. As of May 31, 2022 and 2021, the Company had working capital of approximately \$7,416,000 and \$7,931,000, respectively. We believe that the aggregate of our existing cash and cash equivalents is sufficient to meet our operating cash requirements and strategic objectives for growth for at least the next year. To satisfy our capital requirements, including ongoing future operations, we may seek to raise additional financing through debt and equity financings.

Operating Activities

During fiscal 2022, cash used in operating activities were approximately \$486,000, as compared to \$5,252,000 for fiscal 2021. The primary factors that contributed to this was a loss of approximately \$4,531,000, a decrease in inventory reserves of \$772,000, and a decrease in the allowance on accounts receivable of \$684,000. These were partially offset by a decrease in accounts receivable of \$1,365,000, a decrease in inventories of \$1,562,000, an increase in accounts payable and accrued expenses of \$389,000, and non-cash expenses of approximately \$1,855,000.

During fiscal 2021, the Company had a net loss of approximately \$7,446,000, an increase in accounts receivable of \$456,000, an increase in inventories of \$1,906,000, and an increase in prepaid expenses of \$1,139,000. These were offset by an increase in accrued compensation of approximately \$110,000, a non-cash stock option expense of \$1,355,000 and depreciation and amortization of \$138,000.

Investing Activities

During fiscal 2022, cash used in investing activities were approximately \$170,000, as compared to \$296,000 for fiscal 2021. During fiscal 2022, the Company purchased approximately \$57,000 of property and equipment and had \$113,000 in expenditures related to patents. During fiscal 2021, the Company purchased approximately \$136,000 of property and equipment and \$160,000 in expenditures related to patents.

Financing Activities

Cash provided by financing activities for fiscal 2022 were approximately \$2,395,000 as compared to \$1,114,000 for fiscal 2021. In fiscal 2022 and 2021, the Company had proceeds from the exercise of stock options of approximately \$77,000 and \$102,000, respectively. During fiscal 2022 and 2021, the Company received approximately \$2,317,000 and \$1,011,000, respectively, in net proceeds from the sale of common stock. The common stock sold and issued in fiscal 2021 and 2022 was issued under the S-3 “shelf” Registration Statement base prospectus filed with the SEC on July 21, 2020 (the “2020 Shelf Registration Statement”) and declared effective by the SEC on September 30, 2020, and under the prospectus supplement filed with the SEC on January 22, 2021 (“2021 Prospectus Supplement”) (See Shareholders’ Equity and Subsequent Events in the notes to the consolidated financial statements for further details about SEC registrations).

The 2020 Shelf Registration Statement registers common shares that may be issued by the Company in a maximum aggregate amount of up to \$90,000,000. On January 22, 2021, we filed the 2021 Prospectus Supplement for the sale of up to \$15,000,000 of shares of our common stock in an at-the-market offering under the 2020 Shelf Registration Statement, of which \$9,609,945 remains available for sale under the 2021 Prospectus Supplement. As of August 29, 2022, the date on which this Annual Report on Form 10-K for the fiscal year ended May 31, 2022, is filed with the SEC, our 2020 Registration Statement remains subject to the offering limits set forth in General Instruction I.B.6 of Form S-3 because our public float is less than \$75 million. For so long as the Company’s public float is less than \$75 million, the aggregate market value of securities sold by the Company under the 2020 Shelf Registration Statement pursuant to Instruction I.B.6 to Form S-3 during any 12 consecutive months may not exceed one-third of the Company’s public float. We have sold \$3,374,328 of our common stock pursuant to General Instruction I.B.6 of Form S-3 in the 12 calendar months preceding the date of filing this Annual Report on Form 10-K. For purposes of this limitation, the aggregate market value of our outstanding common stock held by non-affiliates, or public float, was \$39,995,179, based on 12,193,652 shares of our outstanding common stock held by non-affiliates and a price of \$3.28 per share, which was the price at which our common stock was last sold on The Nasdaq Capital Market on August 22, 2022 (a date within 60 days of the date hereof), calculated in accordance with General Instruction I.B.6 of Form S-3. After giving effect to the \$13,331,726 offering limit imposed by General Instruction I.B.6 of Form S-3, and after deducting the shares we sold within the preceding 12 months, as of the date of filing this Annual Report, we may offer and sell from time to time up to \$9,609,945 under the 2021 Prospectus Supplement.

The Company intends to use the net proceeds from these offerings 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

Subsequent to May 31, 2022, the Company sold 523,977 shares of its common stock under its S-3 “shelf” Registration statement. The average sale price was \$3.46 per share. Net proceeds to the Company were approximately \$1,765,000.

On July 14, 2022, the Company announced they had entered into a General Merchandise Supplier Agreement with Walmart, for the Company’s Aware[®] Breast Self Exam product to be sold in Walmart’s retail system.

OFF BALANCE SHEET ITEMS

There were no off-balance sheet arrangements as of May 31, 2022.

CRITICAL ACCOUNTING POLICIES

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make a number of estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements. Such estimates and assumptions affect the reported amounts of revenues and expenses during the reporting period. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ materially from these estimates under different assumptions or conditions. We continue to monitor significant estimates made during the preparation of our financial statements. On an ongoing basis, we evaluate estimates and assumptions based upon historical experience and various other factors and circumstances. We believe our estimates and assumptions are reasonable under the current conditions; however, actual results may differ from these estimates under different future conditions.

We believe that the estimates and assumptions that are most important to the portrayal of our financial condition and results of operations, in that they require subjective or complex judgments, form the basis for the accounting policies deemed to be most critical to us. These relate to revenue recognition, bad debts, inventory overhead application, inventory reserve, lease liabilities and right-of-use assets. We believe estimates and assumptions related to these critical accounting policies are appropriate under the circumstances; however, should future events or occurrences result in unanticipated consequences, there could be a material impact on our future financial conditions or results of operations. We suggest that our significant accounting policies be read in conjunction with this Management's Discussion and Analysis of Financial Condition and Results of Operations. Please refer to Note 2 for information on Significant Accounting Policies.

REVENUE RECOGNITION

The Company has various contracts with customers. All 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 regularly evaluates the status of these contracts and does not believe that any 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.

SHARE-BASED COMPENSATION

The Company follows the guidance 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 foreseeable 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 exercise 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 grant date fair value of the award is recognized under the straight-line attribution method.

RECENT ACCOUNTING PRONOUNCEMENTS

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

RECLASSIFICATIONS

Certain comparative figures in the 2021 Statement of Operations have been reclassified to conform to the current year's presentation.

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

For year ended May 31, 2022 the Company changed its auditor to Haskell & White LLP. The Company's previous auditor was PKF San Diego, LLP ("PKF"), there were no disagreements between the Company and PKF.

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.

Company management, including the CEO and CFO concluded that, as of May 31, 2022, the Company’s internal control over financial reporting was effective.

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 quarter ended May 31, 2022, 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, 2022, 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 independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent 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 2022 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, 2022.

ITEM 11. EXECUTIVE COMPENSATION

This information is incorporated by reference to the Company's proxy statement for its 2022 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, 2022.

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 2022 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, 2022.

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 2022 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, 2022.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Please refer to the Company's proxy statement for its 2022 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, 2022.

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	First Amended and Restated Certificate of Incorporation of Registrant 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).
3.2	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).
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	Standard Industrial/Commercial Single-Tenant Lease, dated June 18, 2009, by and between Registrant and CNH, LLC 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).
10.2	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).
10.3	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).
10.4	2020 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 21, 2021).
10.5	Form of Executive Stock Option Agreement (attached herein)
21.1	Listing of Subsidiaries (attached herein).
23.1	Consent of Independent Registered Public Accounting Firm (Haskell & White LLP).
23.2	Consent of Independent Registered Public Accounting Firm (PKF San Diego, LLP).
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) under the Exchange Act, adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Exchange Act, adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
32.1	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, as amended.
32.2	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, as amended.
99.3	Registrant 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.
104	Cover Page Interactive Data File.

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, as amended, 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 29, 2022

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

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

Date: August 29, 2022

/s/ Steve Sloan
Steve Sloan
Chief Financial Officer

Date: August 29, 2022

/s/ Allen Barbieri
Allen Barbieri
Director, Vice-Chairman

Date: August 29, 2022

/s/ Jane Emerson, M.D., Ph.D.
Jane Emerson, M.D., Ph.D.
Director

Date: August 29, 2022

/s/ Mark Sirgo, Pharm.D.
Mark Sirgo, Pharm.D.

Date: August 29, 2022

/s/ Catherine Coste, CPA
Catherine Coste, CPA
Director

Date: August 29, 2022

BIOMERICA, INC. AND SUBSIDIARIES
TABLE OF CONTENTS

Reports of Independent Registered Public Accounting Firm	FS-2 – FS-3
CONSOLIDATED FINANCIAL STATEMENTS	
Consolidated Balance Sheets as of May 31, 2022 and 2021	FS-4
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended May 31, 2022 and 2021	FS-5
Consolidated Statements of Shareholders' Equity for the Years Ended May 31, 2022 and 2021	FS-6
Consolidated Statements of Cash Flows for the Years Ended May 31, 2022 and 2021	FS-7
Notes to Consolidated Financial Statements	FS-8 – FS-21

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors
Biomerica, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of **Biomerica, Inc.** (the “Company”) as of May 31, 2022, the related consolidated statements of operations and comprehensive loss, shareholders’ equity, and cash flows for the year then ended, and the related notes (collectively, the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of May 31, 2022, and the consolidated results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matter

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

Evaluation of Inventory Reserves

Critical Audit Matter Description

As of May 31, 2022, the Company recorded reserves for slow-moving and obsolete inventories of approximately \$846,000. As described in Note 2 to the consolidated financial statements, management periodically reviews inventories for excess quantities and obsolescence by evaluating quantities on hand and the physical condition and technical functionality of inventories, as these characteristics may be impacted by anticipated customer demand for current products and new product introductions.

Auditing the Company’s estimates for slow-moving and obsolete inventories was challenging due to the inherently judgmental nature of forecasting future sales and usage of a significant number of diverse inventory components.

How the Critical Audit Matter Was Addressed in the Audit

To test the valuation and accuracy of the Company’s inventory reserve estimates, our audit procedures included:

- Obtaining an understanding of the Company’s inventory reserve estimation processes and key internal controls and assessing their appropriateness;
- Observing and testing the Company’s year-end physical inventory counts;
- Testing the accuracy of key data inputs that are the primary drivers for determining the quantitative inventory reserves; these inputs included inventory quantities on hand, historical and expected sales and usage of inventory components, and estimated inventory reserve percentages; and
- Inquiring of any qualitative adjustments to inventory reserves deemed necessary by management and assessing their appropriateness.

/s/ Haskell & White LLP
HASKELL & WHITE LLP (200)

We have served as the Company’s auditor since 2022.

Irvine, California
August 29, 2022

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 sheet of Biomerica, Inc. (a Delaware Corporation) and Subsidiaries (the "Company") as of May 31, 2021, the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for the year ended May 31, 2021, 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, 2021, and the results of its operations and its cash flows for the year ended May 31, 2021, 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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the May 31, 2021 audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Evaluation of Inventory and Accounts Receivable Allowances

The Company recorded allowances for inventory and accounts receivable of approximately \$1,600,000 and \$840,000, respectively, as of May 31, 2021, primarily related to COVID-19 inventory items that have been slow moving and accounts receivable from foreign customers where collectability is questionable. As described in Note 2, these allowances are adjusted based on management's ongoing evaluations and assessments based on current conditions.

Auditing the Company's estimates for inventory and accounts receivable allowances was challenging due to the assumptions made by management based on anticipated future results of customers and marketplace developments.

We obtained an understanding and evaluated the assumptions, criteria and process used by management to determine the allowances for inventory items and accounts receivable.

To test the valuation and accuracy of allowances for inventory and accounts receivable, our audit procedures included, among others, observation and testing of the cost and the valuation allowance for inventory items on hand, examining recent sales of items, testing of aging of accounts receivable balances, confirmation, and testing of subsequent cash receipts on accounts receivable, and discussions with management.

/s/PKF San Diego, LLP
(formerly PKF, LLP)

We served as the Company's auditor from 2004 to 2021.

San Diego, California
August 27, 2021, except for the effect of the restatement disclosed in Note 11 of the May 31, 2021 consolidated financial statements, as to which the date is October 14, 2021

BIOMERICA, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	May 31,	
	2022	2021
Assets		
Current Assets:		
Cash and cash equivalents	\$ 5,916,983	\$ 4,199,311
Accounts receivable, less allowance for doubtful accounts of \$153,231 and \$837,415 as of May 31, 2022 and 2021, respectively	773,818	1,455,051
Inventories, net	2,416,447	3,206,255
Prepaid expenses and other	320,283	370,290
Total current assets	9,427,531	9,230,907
Property and equipment, net of accumulated depreciation and amortization of \$1,305,360 and \$1,972,357 as of May 31, 2022 and 2021, respectively	214,487	310,520
Right of use assets, net of accumulated amortization of \$724,802 and \$469,077 as of May 31, 2022 and 2021, respectively	1,301,834	1,553,081
Investments	165,324	165,324
Intangible assets, net of accumulated amortization of \$18,994 and \$126,769 as of May 31, 2022 and 2021, respectively	169,516	294,830
Other assets	95,588	264,151
Total Assets	<u>\$ 11,374,280</u>	<u>\$ 11,818,813</u>
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 972,372	\$ 583,380
Accrued compensation	646,944	388,896
Advance from customers	50,670	-
Lease liability, current portion	341,296	327,944
Total current liabilities	2,011,282	1,300,220
Lease liability, net of current portion	1,038,284	1,291,570
Total Liabilities	3,049,566	2,591,790
Commitments and contingencies (Notes 6 and 9)		
Shareholders' Equity:		
Preferred stock, Series A 5% convertible, \$0.08 par value, 571,429 shares authorized, none issued and outstanding as of May 31, 2022 and 2021	-	-
Preferred stock, undesignated, no par value, 4,428,571 shares authorized, none issued and outstanding as of May 31, 2022 and 2021	-	-
Common stock, \$0.08 par value, 25,000,000 shares authorized, 12,867,924 and 12,307,157 issued and outstanding at May 31, 2022 and 2021, respectively	1,029,432	984,571
Additional paid-in-capital	42,446,597	38,836,743
Accumulated other comprehensive loss	(73,936)	(47,956)
Accumulated deficit	(35,077,379)	(30,546,335)
Total Shareholders' Equity	8,324,714	9,227,023
Total Liabilities and Shareholders' Equity	<u>\$ 11,374,280</u>	<u>\$ 11,818,813</u>

See accompanying notes to consolidated financial statements

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

	For the year ended May 31,	
	2022	2021
Net sales	\$ 18,871,409	\$ 7,199,027
Cost of sales	(15,893,991)	(6,832,742)
Gross profit	2,977,418	366,285
Operating expenses:		
Selling, general and administrative	5,698,958	5,671,517
Research and development	1,812,424	2,194,461
Total operating expense	7,511,382	7,865,978
Loss from operations	(4,533,964)	(7,499,693)
Other income:		
Dividend and interest income	26,639	66,863
Interest expense	-	(367)
Total other income	26,639	66,496
Loss before income taxes	(4,507,325)	(7,433,197)
Provision for income taxes	(23,719)	(13,057)
Net loss	\$ (4,531,044)	\$ (7,446,254)
Basic net loss per common share	\$ (0.36)	\$ (0.62)
Diluted net loss per common share	\$ (0.36)	\$ (0.62)
Weighted average number of common and common equivalent shares:		
Basic	12,673,245	11,928,941
Diluted	12,673,245	11,928,941
Net loss	\$ (4,531,044)	\$ (7,446,254)
Other comprehensive loss, net of tax:		
Foreign currency translation	(25,980)	(8,115)
Comprehensive loss	\$ (4,557,024)	\$ (7,454,369)

See accompanying notes to consolidated financial statements

BIOMERICA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
FOR THE YEARS ENDED MAY 31, 2022 AND 2021

	Common Stock		Series A 5% Convertible Preferred Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balances, May 31, 2020, restated	11,740,089	\$ 939,205	321,429	\$ 25,714	\$ 36,388,056	\$ (39,841)	\$ (23,100,081)	\$ 14,213,053
Exercise of stock options	86,750	6,940	-	-	95,315	-	-	102,255
Net proceeds from ATM	158,889	12,712	-	-	998,763	-	-	1,011,475
Foreign currency translation	-	-	-	-	-	(8,115)	-	(8,115)
Conversion of preferred to common stock	321,429	25,714	(321,429)	(25,714)	-	-	-	-
Compensation expense in connection with options granted	-	-	-	-	1,354,609	-	-	1,354,609
Net loss	-	-	-	-	-	-	(7,446,254)	(7,446,254)
Balances, May 31, 2021, restated	12,307,157	984,571	-	-	38,836,743	(47,956)	(30,546,335)	9,227,023
Exercise of stock options	39,500	3,160	-	-	74,200	-	-	77,360
Net proceeds from ATM	521,267	41,701	-	-	2,275,459	-	-	2,317,160
Foreign currency translation	-	-	-	-	-	(25,980)	-	(25,980)
Compensation expense in connection with options granted	-	-	-	-	1,260,195	-	-	1,260,195
Net loss	-	-	-	-	-	-	(4,531,044)	(4,531,044)
Balances, May 31, 2022	12,867,924	\$ 1,029,432	-	\$ -	\$ 42,446,597	\$ (73,936)	\$ (35,077,379)	\$ 8,324,714

See accompanying notes to consolidated financial statements.

BIOMERICA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended May 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (4,531,044)	\$ (7,446,254)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	339,096	138,267
Loss on disposal of property and equipment	52,587	-
Provision for allowance on accounts receivable	(684,184)	766,434
Inventory reserve	(771,736)	1,550,594
Stock option expense	1,260,195	1,354,609
Amortization of right-of-use asset	255,725	237,588
Changes in assets and liabilities:		
Accounts receivable	1,365,417	(455,614)
Inventories	1,561,544	(1,906,013)
Prepaid expenses and other	50,007	1,138,793
Reduction in lease liability	(244,412)	(241,132)
Other assets	168,563	(95,958)
Accounts payable and accrued expenses	388,992	(403,331)
Accrued compensation	258,048	110,269
Advance from customers	50,670	-
Net cash used in operating activities	<u>(480,532)</u>	<u>(5,251,748)</u>
Cash flows from investing activities:		
Expenditure related to intangibles	(113,436)	(159,727)
Purchases of property and equipment	(56,900)	(135,856)
Net cash used in investing activities	<u>(170,336)</u>	<u>(295,583)</u>
Cash flows from financing activities:		
Gross proceeds from sale of common stock	2,401,734	1,177,394
Costs from sale of common stock	(84,574)	(165,919)
Proceeds from exercise of stock options	77,360	102,255
Net cash provided by financing activities	<u>2,394,520</u>	<u>1,113,730</u>
Effect of exchange rate changes in cash	(25,980)	(8,115)
Net increase (decrease) in cash and cash equivalents	<u>1,717,672</u>	<u>(4,441,716)</u>
Cash and cash equivalents at beginning of year	<u>4,199,311</u>	<u>8,641,027</u>
Cash and cash equivalents at end of year	<u>\$ 5,916,983</u>	<u>\$ 4,199,311</u>
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for:		
Income taxes	<u>\$ 23,719</u>	<u>\$ 27,171</u>
Non-cash investing and financing activities:		
Increase in right-of-use asset due to lease extension or establishment	<u>\$ 4,478</u>	<u>\$ 79,159</u>
Increase in lease liability due to lease extension or establishment	<u>\$ 4,478</u>	<u>\$ 79,159</u>
Write off of fixed assets, cost	<u>\$ 819,931</u>	<u>\$ -</u>
Write off of fixed assets, accumulated depreciation	<u>\$ 767,344</u>	<u>\$ -</u>
Write off of intangible assets, cost	<u>\$ 246,756</u>	<u>\$ -</u>
Write off of intangible assets, accumulated amortization	<u>\$ 37,221</u>	<u>\$ -</u>

See accompanying notes to consolidated financial statements

BIOMERICA, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED MAY 31, 2022 AND 2021

NOTE 1: ORGANIZATION

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, nasal 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, development, commercialization and in certain cases regulatory approval, of 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. Our InFoods® IBS product uses a simple blood sample and is designed to identify patient-specific foods that, when removed from the diet, may alleviate IBS symptoms such as pain, bloating, diarrhea and constipation. Instead of broad and difficult to manage dietary restrictions, the InFoods® IBS product works by identifying a patient's above normal immunoreactivity to specific foods. A food identified as positive and causing an abnormal immune response in the patient is simply removed from the diet to help alleviate IBS symptoms.

Our existing medical diagnostic products are sold worldwide primarily in two markets: 1) clinical laboratories and 2) point-of-care (physicians' offices and over-the-counter drugstores like Walmart and Walgreens). The diagnostic test kits are used to analyze blood, urine, nasal or fecal specimens from patients in the diagnosis of various diseases, food intolerances 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 pandemic, in March 2020 we began developing COVID-19 products to indicate if a person has been infected by COVID-19 or is currently infected. While we offer a COVID-19 antibody diagnostic test to determine if a person has previously been infected by the COVID-19 virus, all of our COVID-19 revenues in fiscal 2022 have come from international sales of our COVID-19 antigen tests that use a patient's nasal fluid sample to detect if the patient is currently infected with the virus.

The other existing products that contributed to our 2022 revenues are primarily focused on gastrointestinal diseases, food intolerances, and certain esoteric tests. These diagnostic test products utilize immunoassay technology. Most of 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 United States by the FDA.

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

PRINCIPLES OF CONSOLIDATION

The consolidated financial statements for the years ended May 31, 2022 and 2021, include the accounts of Biomerica, Inc. ("Biomerica") as well as its wholly-owned 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; inventory obsolescence, which is 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, the 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 information. Actual results could materially differ from those estimates.

Due to the Coronavirus global pandemic, the Company's operations have been negatively impacted. The Company has faced disruptions in the following areas, (and may face further challenges): 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 suppliers, 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 ongoing 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.

LIQUIDITY

The Company has incurred net losses and negative cash flows from operations and has an accumulated deficit of approximately \$35.3 million as of May 31, 2022. Management expects to continue to incur significant costs as it advances its trials and development activities. As of May 31, 2022, the Company had cash and cash equivalents of approximately \$5,917,000 and working capital of approximately \$7,416,000.

On January 22, 2021, the Company filed a Prospectus Supplement for purposes of raising up to \$15,000,000 to the base prospectus filed with the SEC on July 21, 2020, and was declared effective by the SEC on September 30, 2020, and an ATM "at the market offering" Agreement.

The Company intends to use the net proceeds from such 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.

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 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, 2022, the Company sold 521,267 shares of its common stock at prices ranging from \$4.02 to \$5.63 under its Form S-3 Registration Statement (File No. 333-239980) and ATM Agreement which resulted in gross proceeds of approximately \$2,402,000 and net proceeds to the Company of \$2,317,000 after deducting commissions for each sale and legal, accounting, and other fees related to the filing of the Form S-3.

As a result of cash and cash equivalents on hand on May 31, 2022, and the ability to raise additional funds through the ATM noted above, management believes the Company has sufficient funds to operate through at least August 2023.

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. The Company also maintains an investment in privately held company (see below).

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, 2022, the Company had approximately \$5,702,000 of uninsured cash. The Company does not believe it is exposed to any significant credit risks.

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.

Our net sales were approximately \$18,871,000 for fiscal 2022 compared to \$7,199,000 for fiscal 2021. For the fiscal years ended May 31, 2022 and 2021, the Company had two distributors, which accounted for a total of 65% and 60% of our net sales, respectively. Of this, for the fiscal years ended May 31, 2022 and 2021, the largest of the distributors mentioned above accounted for 55% and 33%, respectively, of net sales.

[Table of Contents](#)

Total gross receivables on May 31, 2022 and 2021 were approximately \$927,000 and \$2,292,000, respectively. On May 31, 2022 and 2021, the Company had one distributor and two distributors, respectively, which accounted for a total of 50% and 73%, respectively, of gross accounts receivable. Of the 50% as of May 31, 2022, 50% was owed by a distributor in Asia.

For the fiscal years ended May 31, 2022 and 2021, the Company had one vendor, which accounted for 84% and 58%, respectively, of our purchases of raw materials.

GEOGRAPHIC CONCENTRATION

As of May 31, 2022 and 2021, approximately \$621,000 and \$803,000, respectively of Biomerica's gross inventory was located in Mexicali, Mexico, respectively. As of May 31, 2022 and 2021, approximately \$17,000 and \$25,000, respectively of Biomerica's property and equipment, net of accumulated depreciation and amortization, 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 usually 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. 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.

As of May 31, 2022 and 2021, the Company has established a reserve of approximately \$153,000 and \$837,000, respectively, for doubtful accounts.

PREPAIDS

The Company occasionally prepays for items such as inventory, insurance, and other items. These items are reported as prepaids, until either the inventory is physically received or the insurance and other items are utilized.

As of May 31, 2022 and 2021, the prepaids were approximately \$320,000 and \$370,000, respectively, composed of prepayments to insurance and various other suppliers.

INVENTORIES, NET

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.

The following is a summary of approximate net inventories:

	May 31,	
	2022	2021
Raw materials	\$ 1,717,000	\$ 1,812,000
Work in progress	763,000	1,687,000
Finished products	782,000	1,324,000
Total gross inventory	\$ 3,262,000	\$ 4,823,000
Inventory reserve	(846,000)	(1,617,000)
Net inventory	\$ 2,416,000	\$ 3,206,000

Reserves for inventory obsolescence are recorded as necessary to reduce obsolete inventory to estimated net realizable value or to specifically reserve for obsolete inventory. As of May 31, 2022 and 2021, inventory reserves were approximately \$846,000 and \$1,617,000, respectively. During the fiscal 2022 the Company disposed of COVID-19 antibody inventory that wasn't sellable, this has been partially reserved for in fiscal 2021. The reduction in our inventory reserve relates to the COVID-19 antibody disposal. The Company continues to sell COVID-19 antigen tests.

PROPERTY AND EQUIPMENT, NET

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 approximately \$100,000 and \$105,000 for the years ended May 31, 2022 and 2021, respectively.

INTANGIBLE ASSETS, NET

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 approximately \$239,000 and \$34,000 for the years ended May 31, 2022 and 2021, 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. As of May 31, 2022 and 2021, an impairment adjustment was made of \$210,000 and \$0, respectively.

INVESTMENTS

From time-to-time, the Company makes investments in privately held companies. Investments represent the Company's investment in a Polish distributor, which is primarily engaged in distributing medical products and devices. The Company owns approximately 6% of the investee and, accordingly, applies the cost method holdings to account for the investment. The Company invested approximately \$165,000 into the Polish distributor.

Equity holdings in nonmarketable unconsolidated entities in which the Company is not able to exercise significant influence ("Cost Method Holdings") are accounted for at the Company's initial cost, minus any impairment (if any), plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar holding or security of the same issuer. Dividends received are recorded as other income.

The Company assesses its equity holdings for impairment whenever events or changes in circumstances indicate that the carrying value of an equity holding may not be recoverable. Management reviewed the underlying net assets of the Company's equity method holding as of May 31, 2022 and determined that the Company's proportionate economic interest in the entity indicates that the equity holding was not impaired. There were no observable price changes in orderly transactions for identical or a similar holding or security of the Company's Cost Method Holding during the year ended May 31, 2022.

SHARE-BASED COMPENSATION

The Company follows the guidance 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 foreseeable 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 exercise 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 grant date fair value of the award is recognized under the straight-line attribution method.

The Company expensed approximately \$1,260,000 and \$1,355,000 of stock-based compensation during the years ended May 31, 2022 and 2021, respectively.

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

	For the year ended May 31,	
	2022	2021
Dividend yield	0%	0%
Expected volatility	102.54 - 105.48%	71.19 - 107.53%
Risk free interest rate	0.97-2.75%	0.34-1.18%
Expected term	5.50-6.25 Years	5.50-6.25 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 regularly evaluates the status of these contracts and does not believe that any additional discounts will be given through the end of the contract periods. Services for 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 an approximate breakdown of revenues according to primary markets to which the products are sold:

	For the year ended May 31,	
	2022	2021
Physician's office	\$ 14,259,000	\$ 2,801,000
Clinical lab	3,064,000	3,077,000
Over-the-counter	1,089,000	766,000
Contract manufacturing	459,000	555,000
Total	\$ 18,871,000	\$ 7,199,000

See Note 8 for additional information regarding geographic 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 approximately \$1,812,000 and \$2,194,000 of research and development costs during the years ended May 31, 2022 and 2021, 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. On May 31, 2022 and 2021, in accordance with ASC 740, the Company has a valuation allowance for substantially all of its net deferred tax assets. During the fiscal year ended May 31, 2022, this valuation allowance was increased to \$6,967,000, which fully covers the net tax asset of \$6,967,000.

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. 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 \$76,000 and \$10,000 for the years ended May 31, 2022 and 2021, 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 foreign currency transactions that are included in the consolidated statements of operations for the years ended May 31, 2022 and 2021.

RIGHT-OF-USE ASSETS AND LEASE LIABILITY

In February 2016, the Financial Accounting Standards Board ("FASB") issued an accounting standard 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 are classified as financing or operating which will drive the expense recognition pattern. The Company has elected to exclude short-term leases. The Company adopted this guidance as of June 1, 2019, the required effective date, which resulted in a right-of-use asset being recorded of approximately \$1,943,000 and a lease liability being recorded of approximately \$1,981,000. On April 9, 2021, the Company exercised its second option to extend its lease for an additional five years. As part of that lease extension agreement, the Company was granted an additional right to extend its lease for five years, up through August 2031. However, given the recent growth in the Company's operations, and the expectation that operations will continue to grow in the near future, the Company believes that it will be necessary to relocate into larger facilities by the end of the current lease term. Therefore, the Company has elected to not include the additional five-year extension option, from August 2026 to August 2031, into its right-of-use asset or its lease liability accounts. For additional information, see Note 9-Commitments and Contingencies. 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, 2022 and 2021 were 2,321,616 and 2,081,366, respectively.

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. Items of other comprehensive loss consist solely of foreign currency translation adjustments for the years ended May 31, 2022 and 2021.

RECENT ACCOUNTING PRONOUNCEMENTS

Recent ASU's issued by the FASB and guidance issued by the SEC did not, or are not believed by management to, have a material effect on the Company's present or future consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, "Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments." This ASU will require the measurement of all expected credit losses for financial assets, including trade receivables, held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. The guidance was initially effective for the Company for annual reporting periods beginning after December 15, 2019, and interim periods within those fiscal years. In November 2019, the FASB issued ASU 2019-10, "Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates," which, among other things, defers the effective date of ASU 2016-13 for public filers that are considered smaller reporting companies as defined by the Securities and Exchange Commission to fiscal years beginning after December 15, 2022, including interim periods within those years. Early adoption is permitted. The Company is currently reviewing the requirements of this ASU to determine its impact on the Company's consolidated results of operations and financial position.

RECLASSIFICATIONS

Certain comparative figures in the 2021 Statement of Operations have been reclassified to conform to the current year's presentation.

NOTE 3: PROPERTY AND EQUIPMENT, NET

The following is an approximate breakdown of property and equipment, net of accumulated depreciation:

	May 31,	
	2022	2021
Equipment	\$ 1,292,000	\$ 1,850,000
Furniture, fixtures and leasehold improvements	227,000	433,000
Less accumulated depreciation	(1,305,000)	(1,972,000)
Net property and equipment	\$ 214,000	\$ 311,000

NOTE 4: INTANGIBLE ASSETS, NET

The following is an approximate breakdown of intangible assets, net of accumulated amortization:

	May 31,	
	2022	2021
Licenses	\$ -	\$ 182,000
Patents	189,000	240,000
Less accumulated amortization-licenses	-	(107,000)
Less accumulated amortization-patents	(19,000)	(20,000)
Intangible assets, net	\$ 170,000	\$ 295,000

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

2023	\$ 13,000
2024	13,000
2025	13,000
2026	13,000
2027	13,000
Thereafter	105,000
Total	\$ 170,000

NOTE 5: ACCOUNTS PAYABLE AND ACCRUED EXPENSES

The following is an approximate breakdown of accounts payable and accrued expenses balances:

	May 31,	
	2022	2021
Accounts payable	\$ 736,000	\$ 431,000
Accrued expenses	236,000	152,000
Total	\$ 972,000	\$ 583,000

As of May 31, 2022 and 2021 the Company had two vendors and one vendor, respectively, which accounted for 69% and 17%, respectively, of accounts payable.

NOTE 6: SHAREHOLDERS' EQUITY

STOCK OPTION AND RESTRICTED STOCK PLANS

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.

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") and on December 11, 2020, the shareholders of the Company approved The Plan. 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.

Stock option expense during fiscal 2022 was approximately \$1,260,000. This included, by department, \$954,000 for administrative, \$159,000 for production, \$80,000 for research and development and \$67,000 for sales and marketing.

Stock option expense during fiscal 2021 was approximately \$1,355,000. This included, by department, \$957,000 for administrative, \$205,000 for production, \$125,000 for research and development and \$68,000 for sales and marketing.

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, 2020	1,789,251	\$0.82-\$8.18	\$ 2.75
Options granted	430,616	\$5.14-\$8.70	\$ 6.73
Options exercised	(86,750)	\$0.82-\$3.62	\$ 1.20
Options canceled or expired	(51,751)	\$2.35-\$8.18	\$ 4.77
Options outstanding at May 31, 2021	2,081,366	\$0.82-\$8.70	\$ 3.59
Options granted	344,000	\$4.25-\$4.46	\$ 4.43
Options exercised	(39,500)	\$1.20-\$3.62	\$ 1.99
Options canceled or expired	(64,250)	\$1.61-\$8.18	\$ 4.41
Options outstanding at May 31, 2022	2,321,616	\$0.82-\$8.70	\$ 3.72

[Table of Contents](#)

The weighted average fair value of options granted during 2022 and 2021 were \$4.43 and \$6.73, respectively. The aggregate intrinsic value of options exercised during 2022 and 2021 was approximately \$90,000 and \$501,000, respectively. The aggregate intrinsic value of options outstanding on May 31, 2022 and 2021 was approximately \$1,838,000 and \$2,132,000, respectively. The aggregate intrinsic value of options vested and exercisable on May 31, 2022 and 2021 was approximately \$1,731,000 and \$1,872,000, respectively.

The number of non-vested stock options included in the table above is as follows:

	Number of shares	Stock options weighted average grant date fair value
Non-vested shares at May 31, 2021	793,241	\$ 5.54
Granted	344,000	4.43
Vested	(347,279)	5.40
Forfeited	(43,500)	5.22
Non-vested shares at May 31, 2022	<u>746,462</u>	<u>\$ 5.11</u>

On May 31, 2022, total compensation cost related to non-vested stock option awards not yet recognized totaled approximately \$1,982,000. The weighted-average period over which this amount is expected to be recognized is 2.32 years. The weighted average remaining contractual term of options that were exercisable on May 31, 2022, was 5.47 years.

The following summarizes information about all the Company's stock options outstanding on May 31, 2022. These options are comprised of those granted under the 2014, 2017 and 2020 plans.

RANGE OF EXERCISE PRICES	NUMBER OUTSTANDING MAY 31, 2022	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE IN YEARS	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER EXERCISABLE AT MAY 31, 2022	WEIGHTED AVERAGE EXERCISE PRICE
\$0.82-\$1.52	456,000	3.33	\$1.04	456,000	\$1.04
\$2.25-\$4.25	1,015,750	6.14	\$2.90	852,500	\$2.88
\$4.34-\$8.70	849,866	8.75	\$6.13	266,654	\$7.06

COMMON STOCK ACTIVITY

On January 22, 2021, the Company filed a Prospectus Supplement, for purposes of raising up to \$15,000,000 to the base prospectus filed with the SEC on July 21, 2020, and declared effective by the SEC on September 30, and an ATM Agreement.

On May 21, 2021, in conjunction with the Company's 2020 Stock Incentive Plan, that was approved by shareholders at the Company's annual meeting in December 2020, the Company filed an S-8 Registration Statement to register up to 900,000 shares of the Company's common stock that could be issued under this Plan.

Under ATM Agreements, 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, 2022, the Company sold 521,267 shares of its common stock at prices ranging from \$4.02 to \$5.63 under its Form S-3 Registration Statement (File No. 333-239980) and ATM Agreement which resulted in gross proceeds of approximately \$2,402,000 and net proceeds to the Company of \$2,317,000 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, 2021, the Company sold 158,889 shares of its common stock at prices ranging from \$7.06 to \$7.79 under its Form S-3 Registration Statement (File No. 333-239980) and ATM Agreement which resulted in gross proceeds of approximately \$1,177,000 and net proceeds to the Company of \$1,011,000 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, 2022, options to purchase 39,500 shares of common stock were exercised at prices ranging from \$1.20 to \$3.62. Total net proceeds to the Company were approximately \$77,000.

During the year ended May 31, 2021, 321,429 shares of common stock were converted from Preferred Stock as described below in "Preferred Stock Activity".

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 accrued annual preferred dividends at a rate of \$0.175 per Series A 5% Convertible Preferred Share. However, accruing dividends were payable only when, as, and if declared by the Board and the Company had no obligation to pay such accruing dividends.

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 571,429 common shares issued, or to be issued, to Palm upon conversion of the Convertible Preferred Stock into common shares. On September 30, 2020, the Company received a Notice of Effectiveness from the Securities and Exchange Commission for registration of these shares. On January 21, 2021, Palm Converted their remaining 321,429 Convertible Preferred Shares into registered common shares. On May 30, 2021, the Company had no shares of Preferred Stock outstanding. Under the terms of the Preferred Stock Purchase Agreement, none of the cumulative Dividends were paid to Palm during the period they owned the Preferred Stock. Once converted to common shares, Palm lost all rights to receive any past cumulative dividends.

NOTE 7: INCOME TAXES

Provision for income taxes for the years ended May 31 consists of the following:

	For the year ended May 31,	
	2022	2021
Current:		
U.S. Federal	\$ -	\$ -
Foreign Taxes Subsidiaries	(23,000)	(12,000)
State and local	(1,000)	(1,000)
Total current	(24,000)	(13,000)
Deferred:		
U.S. Federal	-	-
State and local	-	-
Total deferred	-	-
Income tax expense	\$ (24,000)	\$ (13,000)

Provision for income taxes differs from the amounts computed by applying the U.S. Federal income tax rate applicable for each year (21% for 2022 and 2021) to pretax income as a result of the following:

	For the year ended May 31,	
	2022	2021
Computed "expected" tax benefit	\$ 947,000	\$ 1,561,000
Increase (reduction) in income taxes resulting from:		
Change in valuation allowance	(1,022,000)	(2,292,000)
State income taxes, net of federal benefit	300,000	217,000
Research and development tax credits	50,000	456,000
Permanent tax differences and other	(217,000)	(88,000)
Stock based compensation benefit	11,000	145,000
Foreign taxes of subsidiaries	(113,000)	(12,000)
Income tax expense	\$ (24,000)	\$ (13,000)

The tax effect of significant temporary differences is presented below:

	May 31,	
	2022	2021
Deferred tax assets:		
Accounts receivable, principally due to allowance for doubtful accounts	\$ 43,000	\$ 200,000
Inventory valuation	237,000	387,000
Compensated absences	120,000	85,000
Net operating loss carryforwards	4,349,000	3,194,000
Tax credit carryforwards	1,096,000	1,055,000
Deferred rent expense/Capitalized leases	20,000	15,000
Stock Options	1,035,000	613,000
Losses of foreign subsidiaries & Other, net	41,000	370,000
Accumulated depreciation and amortization	26,000	(15,000)
Total deferred tax assets	6,967,000	5,904,000
Less valuation allowance	(6,967,000)	(5,904,000)
Net deferred tax asset	\$ -	\$ -

The Company has provided a valuation allowance of approximately \$6,967,000 and \$5,904,000 as of May 31, 2022 and 2021, respectively. The net change in the valuation allowance for the years ended May 31, 2022 and 2021, was an increase of \$1,063,000 and \$2,292,000, respectively.

On May 31, 2022, the Company has Federal income tax net operating loss carryforwards of approximately \$17,116,000. On May 31, 2022, the Company has California state income tax net operating loss carryforwards of approximately \$10,805,000. For tax reporting purposes, operating loss carryforwards are available to offset future taxable income; such carryforwards expire in varying amounts beginning in 2023 and 2037 for federal and state purposes, respectively. Federal net operating losses beginning in 2018 have no expiration date.

On May 31, 2022, the Company has Federal research and development tax credit carryforward of approximately \$784,000. The Federal credits begin to expire in 2027. The Company also had similar credit carryforwards for state purposes of \$395,000 on May 31, 2022, which don't expire.

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, 2022, 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 2018.

NOTE 8: GEOGRAPHIC INFORMATION

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

	For the year ended May 31,			
	2022		2021	
Asia	\$ 13,375,000	71%	\$ 1,908,000	26%
Europe	4,339,000	23%	4,301,000	60%
North America	997,000	5%	548,000	8%
South America	90,000	1%	250,000	3%
Middle East	70,000	0%	192,000	3%
Total	\$ 18,871,000	100%	\$ 7,199,000	100%

NOTE 9: COMMITMENTS AND CONTINGENCIES

OPERATING LEASES

The Company leases its facilities. On May 31, 2022, the Company had approximately 22,000 square feet of floor space at its corporate headquarters at 17571 Von Karman Avenue in Irvine, California, 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. On April 9, 2021, the Company exercised its second option to extend its lease for an additional five years. When the Company extended its lease in April 2021, it was also granted an additional five-year lease extension option. The current rent is approximately \$25,000 per month and will increase on September 1, 2022, to \$26,000 per month. The security deposit is approximately \$22,000.

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. The Company has one 10-year option to renew at the end of the initial lease period. The current rent is approximately \$3,400 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.

Total gross rent expense in the United States for fiscal 2022 was approximately \$310,000, and for fiscal 2021 was \$295,000. Rent expense for the Mexico facility for fiscal 2022 and 2021 was approximately \$42,000 and \$25,000, 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 Consolidated Statements of Operations and Comprehensive Loss when they are incurred.

Supplemental cash flow information related to leases for the year ended May 31, 2022:

Operating cash flows from operating leases	\$	338,206
Right-of-use assets obtained in exchange for new operating lease liabilities	\$	-
Weighted average remaining lease term (in years)		4.28
Weighted average discount rate		6.50%

Future minimum lease payments under operating leases on May 31, 2022, are as follows:

Less than 1 year	\$	351,000
1 to 2 years		362,000
2 to 3 years		373,000
3 to 4 years		384,000
4 to 5 years		104,000
Total undiscounted lease payments		1,574,000
Less imputed interest		194,000
Total operating lease liabilities	\$	<u>1,380,000</u>

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, 2022.

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 \$19,000 and \$11,000 is included in cost of sales for the agreement for each of the years ended May 31, 2022 and 2021, respectively. Sales of products manufactured under these agreements comprise approximately 1.5% and 1.5% of total sales for the years ended May 31, 2022 and 2021, 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 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. The required FDA approval was not obtained by December 31, 2019, however, neither party has terminated the agreement. Once the IBS Product is cleared by the United States FDA, 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.

The terms of the Telcon Agreement provide up to \$1.25 million in future exclusivity fees to be possibly paid to Biomerica based on certain milestones including Biomerica’s starting clinical trials in the United States, receipt of U.S. 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 stock 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 Korea, 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. During the quarter ended August 31, 2020, a second amendment was signed extending the required FDA approval date to December 31, 2021. The required FDA approval date hasn’t been delivered however, neither party has terminated the agreement.

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. 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 Emergency Use Authorization (“EUA”) with the FDA for the sale of a product developed by the Company that is based on this technology. The FDA has still not approved the Company’s Emergency Use Authorization for this product to be sold. As such, no royalty fees have been paid yet on these agreements. The Company is selling a COVID-19 rapid test outside of the United States, which is unrelated to the EUA product discussed above.

On May 7, 2020, the Company entered into an exclusive license agreement (the “UC License Agreement”) 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 UC-San Diego 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 UC 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 Agreement provides 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 was paid 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.

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 approximately \$82,000. The work started in October 2017 with charges for work performed being invoiced and paid monthly. This study ended in February 2020. Approximately \$17,000 in fees has been accrued for unbilled charges as of May 31, 2022.

The Company entered into a Clinical Trial Agreement with a research institute 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. This study ended in March 2022. Approximately \$28,000 in fees has been accrued for unbilled charges as of May 31, 2022.

NOTE 10: SUBSEQUENT EVENTS

Subsequent to May 31, 2022, as of the filing of Form 10-K, the Company sold 523,977 shares of its common stock under its Form S-3 “shelf” Registration statement. The average sale price was \$3.46 per share. Net proceeds to the Company were approximately \$1,765,000.

On July 14, 2022, the Company announced they had entered into a General Merchandise Supplier Agreement with Walmart, for the Company’s Aware[®] Breast Self Exam product to be sold in Walmart’s retail system.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-239980), as amended, and the Registration Statements on Form S-8 (Nos. 333-179443, 333-204410, 333-224836 and 333-256377) of Biomerica, Inc. (the "Company") of our report dated August 29, 2022, relating to our audit of the Company's consolidated financial statements as of May 31, 2022, and for the year then ended, included in the Company's Annual Report on Form 10-K for the year ended May 31, 2022.

/s/ HASKELL & WHITE LLP
HASKELL & WHITE LLP

Irvine, California
August 29, 2022

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. 333-179443, 333-204410, 333-224836 and 333-256377) and Form S-3 (No. 333-239980) of Biomerica, Inc. and Subsidiaries, of our report dated August 27, 2021, except for the effect of the restatement disclosed in Note 11 of the May 31, 2021 consolidated financial statements, as to which the date is October 14, 2021, relating to the consolidated financial statements as of May 31, 2021 and for the year ended May 31, 2021, which appears in this Form 10-K.

/s/ PKF San Diego, LLP

PKF San Diego, LLP
(formerly PKF, LLP)

San Diego, CA
August 29, 2022

**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.

<i>/s/ Zackary S. Irani</i>
Zackary S. Irani Chief Executive Officer Date: August 29, 2022

**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, Steve Sloan, 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/ Steve Sloan

Steve Sloan

Chief Financial Officer

Date: August 29, 2022

**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, 2022, 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, as amended:

- 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
<i>Zackary S. Irani</i>
Chief Executive Officer
Date: August 29, 2022

**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, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steve Sloan, 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, as amended:

- 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.

<i>/s/ Steve Sloan</i>
Steve Sloan Chief Financial Officer
Date: August 29, 2022