

BIOMERICA INC  
Form 10-K  
August 29, 2018

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-K**

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

**For The Fiscal Year Ended May 31, 2018 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: 0-8765**

**BIOMERICA, INC.**

(Exact Name of registrant as specified in its charter)

**Delaware**

**95-2645573**

(State or other jurisdiction of

(I.R.S. Employer  
Identification No.)

Incorporation of organization)

**17571 Von Karman Avenue, Irvine, CA**

**92614**

(Address of principal executive offices)

(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

---

Edgar Filing: BIOMERICA INC - Form 10-K

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act  
Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Act. Yes ☒ No ☐

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

Indicate by check whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation (paragraph 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (paragraph 229.405 of this chapter) is not contained herein, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large Accelerated Filer ☐  
Non-Accelerated Filer ☐

Accelerated Filer ☐  
Smaller Reporting Company ☒

Edgar Filing: BIOMERICA INC - Form 10-K

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 6,497,626 shares held by non-affiliates and the closing price of \$3.44 per share for Common Stock in the over-the-counter market as of November 30, 2017): \$22,351,833.

Indicate the number of shares outstanding of each of the registrant's common stock, par value \$0.08, outstanding as of August 29, 2018: 8,953,832

DOCUMENTS INCORPORATED BY REFERENCE: Part III contains information incorporated by reference to the Company's proxy statement for its 2018 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, 2018. The Exhibit Index incorporates by reference various documents previously filed with the Securities and Exchange Commission.

## **PART I**

### **ITEM 1. BUSINESS**

#### **BUSINESS OVERVIEW**

##### **THE COMPANY**

Biomerica, Inc. ("Biomerica", the "Company", "we", "us" or "our") was incorporated in Delaware in September 1971 as Nuclear Medical Systems, Inc. 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.

The Company develops, manufactures, and markets medical diagnostic products designed for the early detection and monitoring of chronic diseases and medical conditions. Our medical diagnostic products are sold worldwide in two markets: 1) clinical laboratories and 2) point of care (physicians' offices and over-the-counter drugstores). Our diagnostic test kits are used to analyze blood, urine, or fecal specimens from patients in the diagnosis of various diseases 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.

We primarily focus on products for gastrointestinal diseases, food intolerances, diabetes and certain esoteric tests. These diagnostic test products utilize immunoassay technology. Some of these products have not been submitted for clearance by the *Food and Drug Administration* ( FDA ) or each country's equivalent for diagnostic use, but can still be sold in various foreign countries for research use without this approval.

Technological advances in medical diagnostics have made it possible to perform diagnostic tests within the home and the physician's office (the point of care), rather than in the clinical laboratory. One of our objectives has 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 and professional rapid diagnostic products help to manage existing medical conditions and may save lives through early detection and prompt diagnosis. In the past, tests of this kind required the services of medical technologists and sophisticated instrumentation. Frequently, results were 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 no instrumentation, give reliable results in minutes and can be performed with confidence in the home or the physician's office.

Biomerica maintains its headquarters in Irvine, California where it houses administration, product development, sales and marketing, customer services and some manufacturing operations. A part of Biomerica's manufacturing and assembly operations is located in Mexicali, Mexico, in order to reduce the cost of manufacturing and compete more effectively worldwide. The Company expends considerable funds in the effort to ready certain new products for market (both internally developed and licensed from others). We utilize technical personnel to conduct product improvement and technical transfer development activities, as well as explore potential new technologies that the Company may wish to develop. We are currently pursuing the development of two tests for the gastrointestinal market.

## **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 production (primarily a portion of our packaging and assembly) to that facility. From 2003 to 2016, Biomerica subleased facilities from and subcontracted with Lancer Orthodontics (a former subsidiary) to provide labor and other services. In November 2016, Biomerica de Mexico, our subsidiary, entered into a lease agreement directly with the landlord and commenced operating independently as a manufacturing entity. All ties with Lancer were severed completely by May 31, 2017.

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 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 which ensures 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. Based on our experience, we do not believe that material availability in the foreseeable future will be a problem.

## RESEARCH AND DEVELOPMENT

We are currently developing and pursuing the regulatory approval of two tests for the gastrointestinal market. Our increase in research and development spending is due to our focus on these tests and studies to demonstrate the feasibility of possible FDA clearance for such tests. The Company also utilizes technical personnel to conduct other development activities and improve existing products, as well as explore potential new technologies that the Company may wish to develop. Research and development expenses include the costs of materials, supplies, personnel, consultants, legal fees, facilities and equipment as well as outside contract services. Consolidated research and development expenses incurred by Biomerica for the years ended May 31, 2018 and 2017 aggregated \$1,398,368, and \$1,130,635, respectively.

The Company has developed a unique diagnostic guided therapy (DGT) that is designed to allow physicians to identify patient-specific foods (e.g. pork, milk, onions, sugar, chickpeas, etc.), that when removed from the diet, may alleviate or improve an individual's symptoms of IBS. The Company is also conducting research to produce DGTs to several other GI diseases including functional dyspepsia, IBD, and GERD. The product is called InFoods® IBS and is designed for both point-of-care testing (allowing physicians to perform the test in-office using a finger stick blood sample) and for clinical labs. A billable CPT code that can be used by both clinical labs and physicians' offices is already available for InFoods® IBS products.

The Company has also commenced clinical studies to evaluate the performance of its new and proprietary *Helicobacter pylori* (*H. pylori*) test. The clinical studies are being conducted at the University of Southern California (USC), Vanderbilt University, and a European University. The patient clinical studies are expected to take 6 to 12 months to complete. The Company will then need to complete the analytical studies and prepare for submission to the FDA and plans to utilize a 510(k) pathway clearance of the test. Biomerica's test is designed to increase the sensitivity and specificity of *H. pylori* testing and monitoring of treatment.

We are planning to pursue a de novo 510(k) rather than a Premarket Approval Application ( PMA ). De novo clearance is faster and less expensive than the PMA route, which is the most stringent type of device marketing application required by the FDA.

## **MARKETS AND METHODS OF DISTRIBUTION**

Biomerica has approximately 340 current customers for its diagnostic business, of which approximately 100 are foreign distributors, 40 are domestic distributors and the balance are primarily domestic hospital and clinical laboratories, medical research institutions, medical schools, pharmaceutical companies, chain drugstores, wholesalers and physicians' offices.

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).

For the years ended May 31, 2018 and 2017, the Company had one distributor which accounted for 43.3% and 45.2%, respectively, of net consolidated sales.

## **BACKLOG**

At May 31, 2018 and 2017, Biomerica had a backlog of approximately \$268,000 and \$242,000, respectively.



## **RAW MATERIALS**

The principal raw materials utilized by Biomerica consist of various chemicals, serums, reagents and packaging supplies. Almost all of our raw materials are available from several sources, and we are not dependent upon any single source of supply or a few suppliers. However, due to the limited number of suppliers of some materials, especially those such as antibodies, there is always the possibility that the Company may encounter difficulty in the future obtaining key raw materials for its manufacturing processes or that such materials may be exceedingly costly. For the year ended May 31, 2018, two companies combined accounted for 27.7% of the purchases of raw materials. For the year ended May 31, 2017, two companies accounted for 23.0% of the 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.

## **COMPETITION**

Immunodiagnostic products are currently produced by more than 100 companies. Biomerica is not a significant player in the overall market.

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

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

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

Our primary business consists of selling products that are legally defined to be in vitro diagnostic and medical devices. As a result, we are considered to be an in vitro diagnostic and medical device manufacturer, and as such are subject to the regulations of numerous governmental entities. These agencies include the FDA, Environmental Protection Agency, Federal Trade Commission, Occupational Safety and Health Administration, U.S. Department of Agriculture

("USDA"), and Consumer Product Safety Commission. These activities are also regulated by various agencies of the states and localities in which our products are sold. These regulations govern the introduction of new medical devices, the observance of certain standards with respect to the manufacture and labeling of medical devices, the maintenance of certain records, the reporting of potential product problems, and other matters.

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

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

In addition, our facility is required to have a California Medical Device Manufacturing License. The license is not transferable and must be renewed biannually. Approval of the license requires that we be in compliance with QSR, labeling and MDR regulations. Our current license expires on November 19, 2018. These licenses are renewed periodically, and to date we have never failed to obtain a renewal.

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

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

Biomerica is licensed to design, develop, manufacture and distribute in vitro diagnostic and medical devices and is subject to the Code of Federal Regulations, Section 21, parts 800 - 1299. The FDA is the governing body that assesses and issues Biomerica's license to assure that it complies with these regulations. Biomerica is currently licensed, and its last assessment was in February 2015. During the inspection, the FDA noted five observations that were corrected in a timely manner. Biomerica is also registered and licensed with the State of California's Department of Health Services. The last audit with the State of California was in November 2009 and no observations were noted. The Company believes that all Biomerica products sold in the U.S. comply with the FDA and state regulations.

Biomerica's Quality Management System is in compliance with the EN ISO 13485:2003. EN ISO 13485:2003 is an internationally recognized standard in which companies establish their methods of operation and commitment to quality.

## **SEASONALITY OF BUSINESS**

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

## **INTERNATIONAL BUSINESS**

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

Year Ended May 31	2018		2017	
Europe	\$	2,023,000/36.4%	\$	2,238,000/38.6%
United States		685,000/12.3%		874,000/15.1%
Asia		2,506,000/45.0%		2,412,000/41.7%
S. America		214,000/3.8%		65,000/1.1%
Middle East		132,000/2.4%		186,000/3.2%
Other foreign		4,000/0.1%		17,000/0.3%
Total Sales	\$	5,564,000/100%	\$	5,792,000/100%

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 and import restrictions all could impact sales within certain foreign countries. In addition, these factors could also impact the ability of the Company to collect foreign debts. 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. Foreign diagnostic sales at Biomerica are made primarily through a network of approximately 100 independent distributors in approximately 65 countries.

## **INTELLECTUAL PROPERTY**

We regard the protection of our copyrights, service marks, trademarks and trade secrets as important to our future success. We rely on a combination of copyright, trademark, patents, 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 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.

## **BRANDS, TRADEMARKS, PATENTS, LICENSES**

We registered the tradenames "Fortel", "Isletest", and "GAP" with the Office of Patents and Trademarks on December 31, 1985. We registered the tradename InFoods on December 24, 2016. Our unregistered tradenames are "EZ-Detect", "EZ-H.P" and "EZ-PSA". A trademark for "Aware" was issued and assigned in November 2001 and renewed in 2011. Biomerica has obtained the rights to manufacture and sell certain products. In some cases royalties are paid on the sales of these products. Biomerica anticipates that it will license or purchase the rights to other products or technology in the future. Biomerica has filed twenty two provisional patent applications with regard to new tests to identify possible triggers for causing specific symptoms. The International Search Authority (ISA) has deemed that for one of Biomerica's patents pertaining to Irritable Bowel Syndrome (IBS), all the International Patent Application claims for its composition and methods to identify trigger foods for IBS are novel and non-obvious.

The laws of some foreign countries do not protect our proprietary rights to the same extent as do the laws of the U.S. Effective copyright, trademark and trade secret protection may not be available in such jurisdictions. Our efforts to protect our intellectual property rights may not prevent misappropriation of our content. In addition, there can be no assurance that Biomerica is not violating any third party patents.

In August 2018, the Korean Intellectual Property Office (KIPO) issued a Certificate of Patent covering Biomerica's compositions, devices and methods of IBS sensitivity testing (entitled COMPOSITIONS, DEVICES, AND METHODS OF IBS SENSIVITY TESTING ). The patent specifically applies to Biomerica's InFoods® IBS product, which is currently in a clinical study in the U.S. This patent is the first for the InFoods® patent portfolio, providing patent protection for InFoods® IBS in Korea until November 13, 2035.

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 is included in cost of sales for this agreement for the years ended May 31, 2018 and 2017. Beginning in fiscal 2011, the Company was only required to pay royalties for one of the products due to the fact that the supplier no longer provides materials to make the other product, which was part of the original agreement. Sales of products manufactured under this agreement comprises approximately 2.6% and 2.5% of total sales for the years ended May 31, 2018 and 2017, respectively. The Company may license other products or technology in the future as it deems necessary for conducting business.

## EMPLOYEES

As of May 31, 2018 and 2017, the Company employed 39 employees, one of whom is employed part-time in the United States. Various employees listed in the production department also perform research and development duties as a routine function of their job. The Company also employed three people who are working on a contractual basis. The following is a breakdown between departments:

	2018	2017
Administrative	5	5
Research and Development	6	1
Marketing & Sales	3	3
Production and Operations	25	30
Total	39	39

In addition, Biomerica de Mexico employs 16 people at its Mexico facility. We also engage the services of various outside Ph.D. and M.D. consultants as well as medical institutions for technical support on a regular basis. We are not a party to any collective bargaining agreement and have never experienced a work stoppage. We consider our employee relations to be good.

## ITEM 1A. RISK FACTORS

The risks described below are not the only ones we face. Additional risks 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. 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 Form 10-K, including our financial statements and related notes.

### RISKS RELATED TO OUR BUSINESS

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

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

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

regulatory clearance

changes in the level of competition, such as would occur if one of our competitors introduced a new, better performing or lower priced product to compete with one or more of our products;

changes in the reimbursement systems or reimbursement amounts that end-users may rely upon in choosing to use our products;

changes in economic conditions in our domestic and international markets, such as economic downturns, decreased healthcare spending, reduced consumer demand, inflation and currency fluctuations; changes in government laws and regulations affecting our business;

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; and

changes in the healthcare market including consolidation in our customer base.





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

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

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

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

Since a large part of the Company's sales are to distributors in Europe, the loss of this certification could materially adversely affect the results of the Company.

The Company has a significant investment in its manufacturing facility in Mexico through its subsidiary, Biomerica de Mexico. There is significant risk in operating facilities in a foreign country and there is the possibility that there may be costs involved with this that we cannot foresee at this time.

**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.**

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 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 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 regulations, we could be required to pay sizable fines,

penalties or damages in the event of noncompliance with environmental laws. Any environmental 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 are not covered by insurance.

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

We devote a significant amount of financial and other resources to researching and developing new technologies, new products and new markets. The development, manufacture and sale of diagnostic products require a significant investment of resources. The development of new markets also requires a substantial investment of resources, such as new employees, offices and manufacturing facilities. 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 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.**

As of the years ended May 31, 2018 and 2017, the Company had one distributor which accounted for 43.3% and 45.2%, respectively, of consolidated net sales. As of May 31, 2018, the Company had one customer who accounted for 53.3% of gross accounts receivable. As of May 31, 2017, the Company had two customers who accounted for 54.2% of gross accounts receivable. The loss of these sales could adversely impact the results of the Company. In addition, the loss of the accounts receivable could negatively impact the Company. In addition, the Company has key distributors in Europe, the loss of which could adversely impact sales and results.

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

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

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

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

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

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

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

pending litigation may of itself cause our distributors or end-users to reduce or terminate purchases of our products;

it may consume a substantial portion of our managerial and financial resources;

its outcome would be uncertain and a court may find any third-party patent claims valid and infringed by our products (issuing a preliminary or permanent injunction) that would require us to procure costly licensing arrangements from third parties or withdraw or recall such products from the market, redesign such products offered for sale or under development or restrict employees from performing work in their areas of expertise;

governmental agencies may commence investigations or criminal proceedings against our employees, former employees and us relating to claims of misappropriation or misuse of another party's proprietary rights;

an adverse outcome could subject us to significant liability in the form of past royalty payments, penalties, special and punitive damages, the opposing party's attorneys' fees, and future royalty payments significantly affecting our future earnings; and

failure to obtain a necessary license (upon commercially reasonable terms, if at all) upon an adverse outcome could prevent us from selling our current products or other products we may develop.

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

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

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

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

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

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

There is no assurance that the results of the clinical trials will be positive. A negative clinical trial could effect our ability to obtain regulatory clearances and/or potential licensing partners.

Our results of operations and financial conditions may be adversely affected by the financial soundness of our customers 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. Any inability of customers to pay us for our products and services, or any demands by suppliers for different payment terms, 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 renegotiating their contracts with us. Any reduction in payments by such government sponsored or private payers may adversely affect our earnings and cash flow. Declining economic conditions may also increase our costs.

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.

The Company is developing certain products, the acceptance of which in the medical community is unpredictable at this time. In addition, the Company will need to spend considerable funds in order to introduce the products into the marketplace.



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

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

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

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

The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities in the U.S., principally the FDA and corresponding state and foreign regulatory agencies. Our future performance depends on, among other matters, if, when and at what cost we will receive regulatory approval for new products. Regulatory review can be a lengthy, expensive and uncertain process, making the timing and costs of clearances and approvals difficult to predict. 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 or the placement of limits on the marketing and use of 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 modifications to existing legislation, such as U.S. tax policy, or entirely new legislation, such as the Affordable Healthcare Act ("AHA") in the U.S. Although we cannot fully predict the many ways that healthcare

reform might affect our business. It is unclear whether and to what extent, if at all, other anticipated developments, including changes due to new presidential administration priorities, or changes resulting from healthcare reform, such as a change in the number of people with health insurance, may impact us.

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

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

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

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

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

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

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

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

**If one or more of our products is claimed to be defective, we could be subject to claims of liability and harm to our reputation that could adversely affect our business.**

A claim of a defect in the design or manufacture of our products could have a material adverse effect on our reputation in the industry and subject us to claims of liability for injuries and otherwise. Any substantial underinsured loss resulting from such a claim would have a material adverse effect on our operating results and financial conditions and the damage to our reputation or product lines in the industry could have a material adverse effect on our business.

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

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

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

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

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

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

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

Our products are primarily sold internationally, with the majority of our international sales to our distributors in Asia and Europe. We currently sell and market our products through distributor organizations and sales agents. These 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;

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;

reduced, or lack of, protection for, and enforcement of, intellectual property rights;

political and economic instability in some of the regions where we currently sell our products or that we may expand into in the future;

complex and potentially adverse tax consequences; and

diversion to the U.S. of our products sold into international markets at lower prices.

Currently, all 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.**

We may need to seek additional capital. If this additional financing is obtained through the issuance of equity securities, debt convertible into equity or options or warrants to acquire equity securities, our existing stockholders could experience significant dilution upon the issuance, conversion or exercise of such securities.

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 securities of smaller medical device companies, like ours, has been very unpredictable and may vary in response to:

announcements by us or our competitors concerning technological innovations;

introductions of new products;



FDA and foreign regulatory actions;

developments or disputes relating to patents or proprietary rights;

failure to meet the expectations of stock market analysts and investors;

changes in stock market analyst recommendations regarding our common stock;

changes in healthcare policy in the U.S. or other countries; and

general stock market conditions and other factors unrelated to our operating performance.

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

Trading of our common stock is not significant, therefore sales of a larger volume of the stock could adversely affect the stock price. As of August 26, 2016, the Company's stock has been traded on the Nasdaq Capital Market. Trading of the Company's stock is limited and liquidation of the Company's stock may be difficult as there is a limited market for the Company's stock.

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

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

We have never declared or paid cash dividends on our common stock and do not plan to pay any cash dividends in the near future. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2. PROPERTIES**

The Company leases its office facilities. At May 31, 2018, the Company had approximately 22,000 square feet of floor space at its corporate headquarters at 17571 Von Karman Avenue in Irvine, California, 92614 which it has been leasing since 2009. The lease for its headquarters expired on August 31, 2016. The Company had an option to extend the term of its lease for two additional sixty month periods. On November 30, 2015, the Company exercised its option to extend its lease for an additional sixty month period and entered into the First Amendment to Lease wherein it extended its lease until August 31, 2021. The initial base rent for the lease extension is \$21,000 per month, increasing to \$23,637 through August 31, 2021. The security deposit of \$22,080 remains the same. In November 2016, the Company's Mexican subsidiary, Biomerica de Mexico, entered into a 10-year lease for approximately 8,100 square feet of manufacturing space with initial base rent of \$2,926/month. The Company has one 10-year option to renew at the end of the initial lease period. 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, as headquarters for BioEurope GmbH, its Germany subsidiary.

#### **ITEM 3. LEGAL PROCEEDINGS**

None.

#### **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**

Since June 20, 2002, the Company's stock had been quoted on the OTC Bulletin Board under the symbol "BMRA". On August 23, 2016, Nasdaq (National Association of Securities Dealers Automated Quotations) approved the Company's application to list its common stock on The Nasdaq Capital Market. The Company trades under the trading symbol BMRA. The Company's common stock started trading on Nasdaq on August 26, 2016.

The following table shows the high and low bid prices for Biomerica's common stock for the periods indicated, based upon data reported by Yahoo Finance. Such quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not necessarily represent actual transactions.

Quarter ended:	Bid Prices	
	High	Low
May 31, 2018	\$ 4.73	\$ 3.33
February 28, 2018	\$ 9.32	\$ 3.30
November 30, 2017	\$ 3.85	\$ 2.62
August 31, 2017	\$ 2.90	\$ 2.30
May 31, 2017	\$ 2.74	\$ 1.97
February 28, 2017	\$ 2.99	\$ 1.92
November 30, 2016	\$ 2.88	\$ 1.75
August 31, 2016	\$ 3.24	\$ 1.41

As of May 31, 2018, the number of holders of record of Biomerica's common stock was approximately 823, 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.

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 intends, for the foreseeable future, to retain any earnings to finance the continued operation and expansion of the Company's business.

On June 30, 2017, the Company filed an S-3 Registration Statement primarily for the purposes of raising capital to support its research, development and intellectual property projects. The statement became effective on July 20, 2017. A prospectus was filed December 1, 2017 which stated that up to \$7,000,000 of funds would be raised from time to time under the S-3 Registration Statement with B. Riley, FBR, acting as the agent for these transactions. As of May 31, 2018, a total of \$1,266,871 in net proceeds had been raised, net of subscriptions receivable. The subscription receivable of \$9,062 was received on June 4, 2018.

We did not purchase any of our shares of common stock or other securities during our fiscal year ended May 31, 2018.

The table below provides information relating to our equity compensation plans as of May 31, 2018:

Securities Remaining
Available for Future Issuance

Securities Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options	Compensation Plans Weighted-Average Exercise Price of Outstanding Options	Equity compensation Plans approved by Securities holders	Under Compensation Plans  (Excluding those Reflected in  First Column)

1,138,625

\$1.65

767,125

## ITEM 6. SELECTED FINANCIAL DATA

Not required.

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

EXCEPT FOR HISTORICAL INFORMATION CONTAINED HEREIN, THE STATEMENTS IN THIS FORM 10-K MAY BE FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 21E OF THE SECURITIES EXCHANGE ACT OF 1934 AND SECTION 27A OF THE SECURITIES ACT OF 1933. FORWARD-LOOKING STATEMENTS INVOLVE KNOWN AND UNKNOWN RISKS AND UNCERTAINTIES WHICH MAY CAUSE BIOMERICA'S RESULTS IN FUTURE PERIODS TO DIFFER MATERIALLY FROM FORECASTED RESULTS. THESE RISKS AND UNCERTAINTIES INCLUDE, AMONG OTHER THINGS, THE CONTINUED DEMAND FOR THE COMPANY'S PRODUCTS, AVAILABILITY OF RAW MATERIALS, THE STATE OF THE ECONOMY, RESULTS OF RESEARCH AND DEVELOPMENT ACTIVITIES AND THE CONTINUED ABILITY OF THE COMPANY TO MAINTAIN THE LICENSES AND APPROVALS REQUIRED. THESE AND OTHER RISKS ARE DESCRIBED IN THE COMPANY'S ANNUAL REPORT ON FORM 10-K AND IN THE COMPANY'S OTHER FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION.

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

### **Overview**

Biomerica, Inc. and Subsidiaries (which includes wholly owned subsidiaries, Biomerica de Mexico and BioEurope GmbH) develop, manufacture, and market medical diagnostic products designed for the early detection and monitoring of chronic diseases and medical conditions. Our medical diagnostic products are sold worldwide in two markets: 1) clinical laboratories and 2) point of care (physicians' offices and over-the-counter drugstores). Our diagnostic test kits are used to analyze blood, urine or fecal material from patients in the diagnosis of various diseases, food intolerances and other medical complications, or to measure the level of specific hormones, antibodies, antigens or other substances, which may exist in the human body in extremely small concentrations.

### **RESULTS OF OPERATIONS**

Our consolidated net sales were \$5,564,185 for fiscal 2018 compared to \$5,791,670 for fiscal 2017. This represents a decrease of \$227,485, or 3.9%. The primary reasons for the sales decrease was a result of decreased sales in Europe (\$215,000) and the U.S. (\$189,000) which were offset by increases in Asia of approximately \$94,000. The decrease in sales in Europe was due in part to lower private label sales and the decrease in the U.S. was a result of a decline of

large purchases by a certain drug store which did not do a screening program in fiscal 2018.

Consolidated cost of sales in fiscal 2018 as compared to fiscal 2017 increased from \$3,769,879 to \$3,809,785, or by \$39,906. The percentage of cost of sales relative to sales increased from 65.1%, to 68.5%, due to various factors, primarily due to fixed costs increasing and the establishment of the maquiladora in Mexico which incurred certain start-up fees.

Consolidated selling, general and administrative costs remained fairly constant, increasing in fiscal 2018 as compared to fiscal 2017 from \$1,845,789 to \$1,837,787, or by \$8,002, or 0.4%.

Consolidated research and development expense was \$1,398,368 in fiscal 2018 as compared to \$1,130,635 in fiscal 2017, an increase of \$267,733, or 23.7%, primarily as a result of increased costs related to the possible FDA clearance of new gastrointestinal products and feasibility. See Research and Development for a more extensive description of the research being conducted.

Interest expense remained constant in fiscal 2018 at \$37 as compared to \$282 in fiscal 2017. Interest and dividend income increased from \$46,354 to \$47,764.

## LIQUIDITY AND CAPITAL RESOURCES

As of May 31, 2018, the Company had cash and cash equivalents in the amount of \$1,204,903 as compared to \$1,225,462 of cash and cash equivalents as of May 31, 2017. As of May 31, 2018, and 2017, the Company had working capital of \$3,587,221, and \$3,681,485, respectively.

### *Operating Activities*

During fiscal 2018, cash used in operating activities was \$1,174,217 as compared to \$722,858 in fiscal 2017. The increase in cash used in operating activities of \$451,359 in fiscal 2018 was primarily due to the loss of \$1,465,828, an increase of \$457,269 in inventory and an increase of \$104,652 in prepaids, which was offset by an increase in accounts payable and accrued expenses of \$319,169 and a decline in accounts receivable of \$252,505. During fiscal 2017, cash used in operating activities was \$722,858. The cash used of \$722,858 in fiscal 2017 was primarily due to the loss of \$908,561, an increase of \$132,261 in accounts receivable and an increase of \$82,179 in prepaids, which was offset by a decline in inventory of \$150,475.

### *Investing Activities*

During fiscal 2018, cash used in investing activities was \$130,347 as compared to \$96,085 in fiscal 2017. For both fiscal years this was for the purchase of property and equipment.

### *Financing Activities*

Cash provided by financing activities in fiscal 2018 was \$1,294,307 as compared to \$157,728 in fiscal 2017. In fiscal 2018 and 2017, the Company had proceeds from the exercise of stock options of \$27,436 and \$157,728, respectively. During fiscal 2018, the Company received \$1,266,871 in net proceeds from the sale of common stock through the S-3 Registration Statement, net of subscriptions receivable.

On June 30, 2017, the Company filed an S-3 Registration Statement for the sale up to \$7 million of the Company's Securities to the public. We realized \$1,266,871 in net proceeds from the sale of common stock under this Registration Statement during fiscal 2018. The proceeds are being used for working capital and general corporate purposes, and in particular, for research, development and costs related to securing intellectual property rights. The funds are also being used for capital expenditures, debt repayment, sales and marketing and general and administrative expenses. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we have no current plans, commitments or agreements with respect to any such acquisitions or investments as of the date of this prospectus.



## **OFF BALANCE SHEET ITEMS**

There were no off-balance sheet arrangements as of May 31, 2018.

## **CRITICAL ACCOUNTING POLICIES**

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

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

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

Revenues from product sales are recognized at the time the product is shipped, customarily FOB shipping point, at which point title passes. Revenues are recognized only when collection is reasonably assured. An allowance is established if necessary for estimated returns as revenue is recognized.

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

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

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

We follow authoritative guidance to evaluate whether a valuation allowance should be established against our deferred tax assets based on the consideration of all available evidence using a more likely than not standard. In making such judgments, significant weight is given to evidence that can be objectively verified. We assess our deferred tax assets annually under more likely than not scenarios in which they may be realized through future income. We have determined that although we believe our deferred tax assets will be utilized at a future date, based on our recent losses and plans to continue our research and development, we have established a valuation allowance of \$1,549,000.

## **FACTORS THAT MAY AFFECT FUTURE RESULTS**

You should read the following factors in conjunction with the factors discussed elsewhere in this and our other filings with the Securities and Exchange Commission and in materials incorporated by reference in these filings. The

following is intended to highlight certain factors that may affect the financial condition and results of operations of Biomerica, Inc. and Subsidiaries and are not meant to be an exhaustive discussion of risks that apply to companies such as Biomerica, Inc. and Subsidiaries. Like other businesses, Biomerica, Inc. and Subsidiaries are susceptible to macroeconomic downturns in the United States or abroad, as were experienced recently, that may affect the general economic climate and performance of Biomerica, Inc. and Subsidiaries or its customers.

Aside from general macroeconomic downturns, the additional material factors that could affect future financial results include, but are not limited to: Terrorist attacks and the impact of such events; diminished or no access to raw materials that directly enter into our manufacturing process; shipping labor disruption or other major degradation of the ability to ship out products to end users; inability to successfully control our margins which are affected by many factors including competition and product mix; protracted shutdown of the U.S. border due to an escalation of terrorist or counter terrorist activity; any changes in our business relationships with international distributors or the economic climate they operate in; any event that has a material adverse impact on our foreign manufacturing operations may adversely affect our operations as a whole; failure to manage the future expansion of our business could have a material adverse effect on our revenues and profitability; possible costs in complying with government regulations and the delays in receiving required regulatory approvals or the enactment of new adverse regulations or regulatory requirements; numerous competitors, some of which have substantially greater financial and other resources than we do; potential claims and litigation brought by patients or medical professionals alleging harm caused by the use of or exposure to our products; recalls of products; inability to obtain FDA clearance on products or excessive costs incurred in order to obtain such approvals; quarterly variations in operating results caused by a number of factors, including business and industry conditions; and other factors beyond our control. All these factors make it difficult to predict operating results for any particular period.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

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

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

Not required.

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

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

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

None.

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

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

## **EVALUATION OF DISCLOSURE CONTROLS**

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

For the reasons discussed in "Management's Report on Internal Control over Financial Reporting" below, Company management, including the CEO and CFO concluded that, as of May 31, 2018, the Company's internal control over financial reporting was effective. Management has concluded that the consolidated financial statements included in this annual report present fairly, in all material respects, the Company's financial position, results of operations, and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States of America.

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

There have been no changes in our internal control over financial reporting identified in connection with the evaluation that occurred during the last fiscal year that has materially affected, or that is 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, 2018, the Company's internal control over financial reporting was effective based on those criteria.

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

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

## **ITEM 9B. OTHER INFORMATION.**

None.

### **PART III**

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

This information is incorporated by reference to the Company's proxy statement for its 2018 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, 2018.

#### **ITEM 11. EXECUTIVE COMPENSATION**

This information is incorporated by reference to the Company's proxy statement for its 2018 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, 2018.

#### **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 2018 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, 2018.

**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 2018 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, 2018.

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

Please refer to the Company's proxy statement for its 2018 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, 2018.



## 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. *Financial Statements*

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

#### 2. *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.

#### ExhibitDescription

No.

- 3.1 Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on September 22, 1971 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
- 3.2 Certificate of Amendment to Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on February 6, 1978 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
- 3.3 Certificate of Amendment to Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on February 4, 1983 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
- 3.4 Certificate of Amendment to Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on January 19, 1987 (incorporated by reference to Exhibit 3.4 filed with Form 8 Amendment No. 1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended May 31, 1987).
- 3.5 Certificate of Amendment of Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on November 4, 1987 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
- 3.6 Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
- 3.7 Certificate of Amendment of Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on December 20, 1994 (incorporated by reference to Exhibit 3.7 filed with Registrant's Annual Report on Form 10-KSB for the fiscal year ended May 31, 1995).

Edgar Filing: BIOMERICA INC - Form 10-K

- 3.8 First Amended and Restated Certificate of Incorporation of Biomerica, Inc. filed with the Secretary of State of Delaware on August 1, 2000 (incorporated by reference to Exhibit 3.8 filed with the Registrant's Annual Report on Form 10-KSB for the fiscal year ended May 31, 2000).
- 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 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.
- 10.4 2010 Stock Incentive Plan of Registrant (incorporated by reference to Exhibit 10.1 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on February 2, 2012.
- 10.5 2014 Stock Incentive Plan of Registrant (incorporated by reference to Exhibit 10.1 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on May 22, 2015.
- 10.6 2017 Stock Incentive Plan of Registrant (incorporated by reference to Exhibit 10.1 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on May 10, 2018.
- 10.7 Form S-3 Registration Statement and Prospectus (incorporated by reference to Registration Statement on Form S-3 filed with the Securities and Exchange Commission on June 30, 2017 and December 4, 2017, respectively).
- 23.1 Consent of Independent Registered Public Accounting Firm (PKF, LLP).
- 31.1 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.
- 31.2 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.
- 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.
- 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.
- 99.3 Biomerica, Inc. and Subsidiaries Consolidated Financial Statements
- 101.INS XBRL Instance Document.
- 101.SCH XBRL Taxonomy Extension Schema Document.
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document.
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document.
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.

## 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, 2018

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: 8/29/18

/s/ Janet Moore

Date: 8/29/18

Janet Moore,

Secretary, Director, Chief Financial  
Officer

/s/ Francis R. Cano, Ph.D.

Date: 8/29/18

Francis R. Cano, Ph.D.

Director

/s/ Allen Barbieri

Date: 8/29/18

Allen Barbieri

Director, Audit Committee Member

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

Date: 8/29/18

Jane Emerson, M.D., Ph.D

Director, Audit Committee Member

/s/ Mark Sirgo,  
Pharm.D

Date: 8/29/18

Mark Sirgo, Pharm.D.

Director, Audit Committee Member

**BIOMERICA, INC. AND SUBSIDIARIES**

**TABLE OF CONTENTS**

Report of Independent Registered Public  
Accounting Firm

FS-2

Consolidated Balance Sheets as of May 31, 2018 and 2017

FS-3

Consolidated Statements of Operations and Comprehensive Loss  
for the Years Ended May 31, 2018 and 2017

FS-4

Consolidated Statements of Shareholders' Equity for the Years  
Ended May 31, 2018 and 2017

FS-5

Consolidated Statements of Cash Flows for the Years Ended  
May 31, 2018 and 2017

FS-6

Notes to Consolidated Financial Statements

**CONSOLIDATED FINANCIAL  
STATEMENTS**

FS-7 FS-20



**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders  
Biomerica, Inc. and Subsidiaries

Irvine, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Biomerica, Inc. (a Delaware Corporation) and Subsidiaries (the Company) as of May 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for each of the two years in the period ended May 31, 2018, 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 consolidated financial position of the Company as of May 31, 2018 and 2017, and the consolidated results of its operations and its cash flows for each of the two years in the period ended May 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/PKF, LLP

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



San Diego, California

August 29, 2018

FS - 2

---

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

	May 31, 2018	May 31, 2017
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,204,903	\$ 1,225,462
Accounts receivable, less allowance for doubtful accounts of \$57,695 and \$50,129, respectively	799,940	1,060,011
Inventories, net	2,178,777	1,729,121
Prepaid expenses and other	300,409	195,757
Total current assets	4,484,029	4,210,351
<b>PROPERTY AND EQUIPMENT:</b>		
Equipment	1,808,152	1,549,411
Furniture, fixtures and leasehold improvements	204,125	332,519
Total property and equipment	2,012,277	1,881,930
Accumulated depreciation	(1,661,128)	(1,550,073)
Net property and equipment	351,149	331,857
DEFERRED TAX ASSETS	10,000	41,000
INTANGIBLE ASSETS, net	98,923	174,469
INVESTMENTS	165,324	165,324
OTHER ASSETS	113,157	94,989
<b>TOTAL ASSETS</b>	<b>\$ 5,222,582</b>	<b>\$ 5,017,990</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 686,956	\$ 352,000
Accrued compensation	209,852	176,866
Total current liabilities	896,808	528,866
<b>COMMITMENTS AND CONTINGENCIES (NOTE 8)</b>		
<b>SHAREHOLDERS' EQUITY</b>		
Preferred stock, no par value, 5,000,000 authorized shares, no shares issued and outstanding at May 31, 2018		
and 2017	--	--
Common stock, \$.08 par value; 25,000,000 shares authorized; 8,888,011 and 8,511,173 shares issued and		
outstanding at May 31, 2018 and 2017, respectively	711,040	680,893
Additional paid-in capital	20,843,550	19,551,855
Subscriptions receivable	(9,062)	--
Accumulated other comprehensive loss	(26,136)	(15,834)
Accumulated deficit	(17,193,618)	(15,727,790)
Total shareholders' equity	4,325,774	4,489,124
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 5,222,582</b>	<b>\$ 5,017,990</b>

See accompanying notes to consolidated financial statements.



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

FOR THE YEARS ENDED MAY 31,	2018	2017
Net sales	\$ 5,564,185	\$ 5,791,670
Cost of sales	(3,809,785)	(3,769,879)
GROSS PROFIT	1,754,400	2,021,791
OPERATING EXPENSES:		
Selling, general and administrative	1,837,787	1,845,789
Research and development	1,398,368	1,130,635
Total operating expenses	3,236,155	2,976,424
LOSS FROM OPERATIONS	(1,481,755)	(954,633)
OTHER INCOME (EXPENSE):		
Interest expense	(37)	(282)
Interest and dividend income	47,764	46,354
Total other income	47,727	46,072
LOSS BEFORE INCOME TAXES	(1,434,028)	(908,561)
INCOME TAX EXPENSE	(31,800)	--
NET LOSS	\$ (1,465,828)	\$ (908,561)
BASIC NET LOSS PER COMMON SHARE	\$ (0.17)	\$ (0.11)
DILUTED NET LOSS PER COMMON SHARE	\$ (0.17)	\$ (0.11)
WEIGHTED AVERAGE NUMBER OF COMMON AND COMMON EQUIVALENT SHARES		Basic
		8,570,029
		8,329,769
	Diluted	
		8,570,029

8,329,769

NET LOSS

\$

(1,465,828)

\$

(908,561)

OTHER COMPREHENSIVE LOSS:

Foreign currency translation

(10,302)

(2,248)

COMPREHENSIVE LOSS

\$

(1,476,130)

\$

(910,809)

See accompanying notes to consolidated financial statements.

FS - 4

---

**BIOMERICA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**

**YEARS ENDED MAY 31, 2018 AND 2017**

	Accumulated	
	Other	
	Comprehensive	
	Loss	
Additional		Common
		Stock
Paid-in		Subscriptions
Capital		Receivable
		Accumulated
		Deficit
		Total
		Shares
		Amount

Balances, May  
31, 2016

8,169,673

\$  
653,573

\$  
19,399,720

\$  
--

\$  
(13,586)

\$  
(14,819,229)

\$  
5,220,478

Exercise of  
stock options  
341,500

27,320

130,408



--

--

--

157,728

Foreign  
currency  
translation

--

--

--

--

(2,248)

--

(2,248)

Compensation  
expense in

connection  
with options  
granted

--

--

21,727

--

--

--

21,727

Net loss

--

--

--

--

--

(908,561)

(908,561)

Balances, May  
31, 2017

8,511,173

680,893

19,551,855

--

(15,834)

(15,727,790)

4,489,124

Exercise of  
stock options

34,750

2,780

24,656

--

--

--

27,436

Net proceeds  
from ATM

342,088

27,367

1,248,566

--

--

--

1,275,933

Stock  
subscription  
receivable

--

--

--

(9,062)

--

--

(9,062)

Foreign  
currency  
translation

--

--

--

--

(10,302)

--

(10,302)

Compensation  
expense in  
  
connection  
with options  
granted

--

--

18,473

--

--

--

18,473

Net loss

--



--

--

--

--

(1,465,828)

(1,465,828)

Balances, May  
31, 2018

8,888,011

\$

711,040

\$

20,843,550

\$

(9,062)

\$

(26,136)

\$

(17,193,618)

\$

4,325,774

See  
accompanying  
notes to  
consolidated  
financial  
statements.

FS - 5

---

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

For the Years Ended May 31,	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (1,465,828)	\$ (908,561)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	186,601	219,219
Change in provision for allowance for doubtful accounts	7,566	41,724
Inventory reserve	7,613	(16,505)
Stock option expense	18,473	21,727
Decrease in deferred rent liability	15,787	8,070
Decrease in deferred tax asset	31,000	--
Changes in assets and liabilities:		
Accounts receivable	252,505	(132,261)
Inventories	(457,269)	150,475
Prepaid expenses and other	(104,652)	(82,179)
Other assets	(18,168)	(39,336)
Accounts payable and accrued expenses	319,169	10,445
Accrued compensation	32,986	4,324
Net cash used in operating activities	(1,174,217)	(722,858)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(130,347)	(96,085)
Net cash used in investing activities	(130,347)	(96,085)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from sale of common stock, net	1,266,871	--
Proceeds from exercise of stock options	27,436	157,728
Net cash provided by financing activities	1,294,307	157,728
Effect of exchange rate changes on cash	(10,302)	(2,248)
Net decrease in cash and cash equivalents	(20,559)	(663,463)
CASH AND CASH EQUIVALENTS, beginning of year	1,225,462	1,888,925
CASH AND CASH EQUIVALENTS, end of year	\$ 1,204,903	\$ 1,225,462

**SUPPLEMENTAL DISCLOSURE OF CASH-FLOW INFORMATION**

Non-cash investing and financing activities:		
Subscriptions receivable	\$ 9,062	\$ --
Cash paid during the year for:		
Interest	\$ 37	\$ 282
Income taxes	\$ 800	\$ 800

See accompanying notes to consolidated financial statements



**BIOMERICA, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**YEARS ENDED MAY 31, 2018 AND 2017**

**1. ORGANIZATION**

Biomerica, Inc. and Subsidiaries (collectively "the Company") are primarily engaged in the development, manufacture and marketing of medical diagnostic kits.

The Company develops, manufactures, and markets medical diagnostic products designed for the early detection and monitoring of chronic diseases and medical conditions. The Company's medical diagnostic products are sold worldwide in two markets: 1) clinical laboratories and 2) point of care (physicians' offices and over-the-counter drugstores). The diagnostic test kits are used to analyze blood, urine or fecal samples from patients in the diagnosis of various diseases 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.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**PRINCIPLES OF CONSOLIDATION**

The consolidated financial statements for the years ended May 31, 2018 and 2017 include the accounts of Biomerica, Inc. ("Biomerica") as well as its German subsidiary (BioEurope GmbH) and Mexican subsidiary (Biomerica de Mexico). All significant intercompany accounts and transactions have been eliminated in consolidation.

**ACCOUNTING ESTIMATES**

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ( GAAP ) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reported period. Actual results could materially differ from those estimates.

## **FAIR VALUE OF FINANCIAL INSTRUMENTS**

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

## **CONCENTRATION OF CREDIT RISK**

The Company maintains cash balances at certain financial institutions in excess of amounts insured by federal agencies. As of May 31, 2018, the Company had approximately \$632,000 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 foreign markets. For the years ended May 31, 2018 and 2017, the Company had one distributor which accounted for 43.3% and 45.2%, respectively, of consolidated sales. The Company performs ongoing credit evaluations of its customers and requires prepayment in some circumstances. At May 31, 2018, one customer accounted for 53.3% of gross accounts receivable. At May 31, 2017, two customers accounted for 54.2% of gross accounts receivable.

For the year ended May 31, 2018, two companies accounted for 27.7% of the purchases of raw materials. For the year ended May 31, 2017, two companies accounted for 23.0 % of the purchases of raw materials.

## **GEOGRAPHIC CONCENTRATION**

As of May 31, 2018 and 2017, approximately \$657,000 and \$467,000 of Biomerica's gross inventory and approximately \$41,000 and \$15,000, of Biomerica's property and equipment, net of accumulated depreciation, was located in Mexicali, Mexico, respectively.

## **CASH EQUIVALENTS**

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

## **ACCOUNTS RECEIVABLE**

The Company extends unsecured credit to its customers on a regular basis. International accounts are required to prepay until they establish a history with the Company and at that time, they are extended credit at levels based on a number of criteria. Credit levels are approved by designated upper level management. Domestic customers are extended initial \$500 credit limits until they establish a history with the Company or submit credit information. All increases in credit limits are also approved by designated upper level management. Management evaluates receivables on a quarterly basis and adjusts the allowance for doubtful accounts accordingly. Balances over ninety days old are usually reserved for unless collection is reasonably assured.

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

## **INVENTORIES**

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



current period charges and the allocation of fixed production overhead is based on the normal capacity of the production facilities.

Inventories approximate the following at May 31:

	2018	2017
Raw materials	\$ 1,000,000	\$ 830,000
Work in progress	854,000	728,000
Finished products	325,000	171,000
Total	\$ 2,179,000	\$ 1,729,000

Reserves for inventory obsolescence are recorded as necessary to reduce obsolete inventory to estimated net realizable value or to specifically reserve for obsolete inventory that the Company intends to dispose of. As of May 31, 2018 and 2017, inventory reserves were approximately \$52,000 and \$35,000, respectively.

## PROPERTY AND EQUIPMENT

Property and equipment are stated at cost. Expenditures for additions and major improvements are capitalized. Repairs and maintenance costs are charged to operations as incurred. When property and equipment are retired or otherwise disposed of, the related cost and accumulated depreciation or amortization are removed from the accounts, and gains or losses from 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 \$111,055 and \$144,887 for the years ended May 31, 2018 and 2017, respectively.

## INTANGIBLE ASSETS

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

Intangible assets are being amortized using the straight-line method over the useful life, not to exceed 18 years for marketing and distribution rights, 10 years for purchased technology use rights, and 17 years for patents. Amortization amounted to \$75,546 and \$74,332 for the years ended May 31, 2018 and 2017, 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. In July 2012, the Financial Accounting Standards Board ( FASB ) issued another update to ASC 350 Intangibles Goodwill and Other: Testing Indefinite-Lived Intangible Assets for Impairment. This update simplifies the guidance for testing impairment of indefinite-lived intangible assets other than goodwill. During fiscal 2013, the Company adopted the updated guidance in ASC 350 and used the qualitative assessment to determine whether there was any impairment. No impairment adjustment was required as of May 31, 2018 or 2017.

## INVESTMENTS

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

## SHARE-BASED COMPENSATION

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

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

	2018	2017
Dividend yield	0%	0%
Expected volatility	59.8-61.28%	53.64-54.73%
Risk free interest rate	1.61-2.53%	1.08-1.23%
Expected life	3.75-6.0 years	3.75-6.25 years

## REVENUE RECOGNITION

Revenues from product sales are recognized at the time the product is shipped, customarily FOB shipping point, at which point title passes. Revenue is recognized only when collectability is reasonably assured. An allowance is established when necessary for estimated returns as revenue is recognized. As of May 31, 2018 and 2017, the allowance for returns is \$0. In conjunction with sales to certain customers, the Company provides free products upon attaining certain levels of purchases by the customer. The Company accounts for these free products in accordance with ASC 605-50 Revenue Recognition Customer Payments and Incentives and recognizes the cost of the product as part of cost of sales.

## SHIPPING AND HANDLING FEES AND COSTS

Shipping and handling fees billed to customers are required to be classified as net sales, and shipping and handling costs are required to be classified as either cost of sales or disclosed in the notes to the consolidated financial statements. The Company included shipping and handling fees billed to customers in net sales. The Company included shipping and handling costs associated with inbound freight and unreimbursed shipping to customers in cost of sales.

## RESEARCH AND DEVELOPMENT

Research and development costs are expensed as incurred. The Company expensed \$1,398,368 and \$1,130,635 of research and development expenses during the years ended May 31, 2018 and 2017, 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. These temporary differences are measured using enacted tax rates. A valuation allowance is recorded to reduce deferred tax assets to the extent that management considers it is more likely than not that a deferred tax asset will not be realized. In determining the valuation allowance, the Company considers factors such as the reversal of deferred income tax assets, projected taxable income, and the character of income tax assets and tax planning strategies. A change to these factors could impact the estimated valuation allowance and income tax expense. At May 31, 2018 and 2017, in accordance with ASC 740, the Company has a valuation allowance for substantially all of its deferred tax assets. During the fiscal year ended May 31, 2018, this valuation allowance was increased to \$1,549,000.

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

## **ADVERTISING COSTS**

The Company reports the cost of all advertising as expense in the period in which those costs are incurred. Advertising costs were approximately \$1,000 and \$7,000 for the years ended May 31, 2018 and 2017, respectively.

## **FOREIGN CURRENCY TRANSLATION**

The subsidiaries located in Germany and Mexico operate primarily using their local functional currencies. 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. The resulting adjustments to foreign currency loss of \$10,302 and \$2,248 are included in the consolidated statements of operations for the years ended May 31, 2018 and 2017, respectively.

**DEFERRED RENT**

Incentive payments received from landlords are recorded as deferred lease incentives and are amortized over the underlying lease term on a straight-line basis as a reduction of rent expense. When the terms of an operating lease provide for periods of free rent, rent concessions, and/or rent escalations, the Company establishes a deferred rent liability for the difference between the scheduled rent payment and the straight-line rent expense recognized. This deferred rent liability is amortized over the underlying lease term on a straight-line basis as a reduction of rent expense.

**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 amount of anti-dilutive stock options not included in the loss per share calculation for the years ended May 31, 2018 and 2017 were 1,138,625 and 897,000, respectively.

The following table illustrates the reconciliation of the numerators and denominators of the basic and diluted earnings per share computations:

For the Years Ended May 31	2018	2017
Numerator :		
Net loss for basic and diluted net loss per common share	\$ (1,465,828)	\$ (908,561)
Denominator for basic net loss per common share	8,570,029	8,329,769
Effect of dilutive securities:		
Options	--	--
Denominator for diluted net loss per common share	8,570,029	8,329,769
Basic net loss per common share	\$ (0.17)	\$ (0.11)
Diluted net loss per common share	\$ (0.17)	\$ (0.11)

**SEGMENT REPORTING**

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

## **REPORTING COMPREHENSIVE LOSS**

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

## **RECENT ACCOUNTING PRONOUNCEMENTS**

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40), which addresses Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. In connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued (or at the date that the financial statements are available to be issued when applicable). The amendments in this update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. Management adopted the provisions of this statement and is taking them into account in the preparation of the financial statements for the period ended May 31, 2018.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers ( ASU 2014-09 ). ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer at an amount reflecting the consideration it expects to receive in exchange for those goods or services. In adopting, ASU 2014-09, companies may use either a full retrospective or a modified retrospective approach. ASU 2014-09 is effective for the first interim period within annual reporting periods beginning December 15, 2016, and early adoption is not permitted. During August 2015, the FASB voted to defer the effective date of the above mentioned revenue recognition guidance by one year to December 15, 2017 for interim and annual reporting periods beginning after that date and permitted early adoption of the standard, but not before the original effective date of December 15, 2016. Management is evaluating the provisions of this statement and has not determined what impact the adoption of ASU 2014-09 will have on the Company's financial position or results of operations.

In July 2015, the FASB issued ASU 2015-11, Simplifying the Measurement of Inventory ( ASU-2015-11 ). ASU 2015-11 applies to inventory that is measured using first-in, first-out ( FIFO ) or average cost. An entity should measure inventory within the scope of ASU 2015-11 at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The amendments in ASU 2015-11 more closely align the measurement of inventory in accounting principles generally accepted of the United States of America with the measurement of inventory in International Financial Reporting Standards ( IFRS ). ASU 2015-11 is effective for fiscal years beginning after December 31, 2016. Management has implemented the provisions of this statement and does not believe the adoption of ASU 2015-11 had a significant impact on the Company's financial position or results of operations.

On January 5, 2016, the FASB issued ASU 2016-01, Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities ( ASU-2016-01 ). The release affects public and private companies that hold financial assets or owe financial liabilities. ASU-2016-01 will take effect for public companies for fiscal years beginning after December 15, 2017. Management is evaluating the provisions of this statement and has not determined what impact the adoption of ASU- 2016-01 will have on the Company's financial position or results of operations.

On February 25, 2016, the FASB issued ASU 2016-02, Leases (Topic 842) ( ASU-2016-02 ). ASU-2016-02 defines whether a contract is a lease. If it is a lease, the Company is required to recognize the lease assets and liabilities. ASU-2016-02 is effective for public companies for the annual periods beginning after December 15, 2018. Management is evaluating the provisions of this statement and has not determined what impact the adoption of ASU-2016-02 will have on the Company's financial position or results of operations.

On March 30, 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The update includes provisions intended to simplify various aspects of accounting for share-based compensation. ASU-2016-09 will take effect for public companies for the annual periods beginning after December 15, 2016. Management does not believe the adoption of ASU 2016-09 has had a significant impact on the Company's financial position or results of operations.



On August 26, 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. This Update addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU-2016-15 will take effect for public companies for the fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Management is evaluating the provisions of this statement and has not determined what impact the adoption of ASU-2016-15 will have on the Company's financial position or results of operations.

On November 27, 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. This update addresses the fact that diversity exists in the classification and presentation of changes in restricted cash on the statement of cash flows under Topic 230, Statement of Cash Flows. ASU-2016-18 will take effect for public companies for the fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Management is evaluating the provisions of this statement and has not determined what impact the adoption of ASU-2016-18 will have on the Company's financial position or results of operations.

In January 2017 the FASB issued ASU 2017-04, Intangibles—Goodwill and Other (Topic 350), Simplifying the test for Goodwill Impairment. This update addresses how an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. ASU 2017-04 will take effect for public companies for the fiscal years beginning after December 15, 2019. Management is evaluating the provisions of this statement and has not determined what impact the adoption of ASU-2017-04 will have on the Company's financial position or results of operations.

On February 15, 2018, the FASB issued ASU 2018-02, Reclassification of Certain Tax Effects From Accumulated Comprehensive Income (ASU 2018-02). ASU 2018-02 will give companies the option to reclassify stranded tax effects caused by the newly-enacted U.S. TAX Cuts and Jobs Act (TCJA) from accumulated other comprehensive income (ASCI) to retained earnings. ASU 2018-02 will take effect for all companies for the fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Management is evaluating the provisions of this statement and has not determined what impact the adoption of ASU 2018-02 will have on the Company's financial position or results of operations.

On June 20, 2018, the FASB issued ASU 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. ASU 2018-07 is intended to reduce cost and complexity and to improve financial reporting for share-based payments to nonemployees (for example, service providers, external legal counsel, suppliers, etc.). ASU 2018-07 will be effective for public companies for December 31, 2019 financial statements and for nonpublic entities for December 31, 2020 financial statements. Early adoption is permitted, but no earlier than entity's adoption date for ASC Topic 606, Revenue from Contracts with Customers. Management is evaluating the provisions of this statement and has not determined what impact the adoption of ASU-2018-7 will have on the Company's financial position or results of operations.

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

### 3. INTANGIBLE ASSETS, NET

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

	2018	2017
Patents and licenses	\$ 509,485	\$ 509,485
Less accumulated amortization	(410,562)	(335,016)
	\$ 98,923	\$ 174,469

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

2019	\$ 60,861
2020	20,339
2021	12,694
2022	3,304

2023		900
Thereafter		825
Total	\$	98,923

#### 4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

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

	2018	2017
Accounts payable	\$ 655,599	\$ 336,430
Deferred rent	31,357	15,570
	\$ 686,956	\$ 352,000

## 5. SHAREHOLDERS' EQUITY

### STOCK OPTION AND RESTRICTED STOCK PLANS

In August 1999, the Company adopted a stock option and restricted stock plan (the "1999 Plan") which provides that non-qualified options and incentive stock options and restricted stock covering an aggregate of 1,000,000 shares of the Company's unissued common stock may be granted to affiliates, employees or consultants of the Company. As of January 1, of each calendar year, commencing January 1, 2000, this amount is subject to automatic annual increases equal to the lesser of 1.5% of the total number of outstanding common shares, assuming conversion of convertible securities, or 500,000 shares. The 1999 plan expired in November 2009. Options granted under the 1999 Plan were granted at prices not less than 80% of the then fair market value of the common stock and expired not more than 10 years after the date of grant.

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

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

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.

Activity as to stock options outstanding is as follows:

	NUMBER OF	PRICE RANGE	WEIGHTED AVERAGE
	STOCK OPTIONS	PER SHARE	EXERCISE PRICE
Options outstanding at May 31, 2016	1,199,000	\$ 0.43-\$ 1.20	\$ 0.81
Options granted	55,000	\$ 1.52-\$ 1.61	\$ 1.55
Options exercised	(341,500)	\$ 0.43-\$ 1.04	\$ 0.46
Options canceled or expired	(15,500)	\$ 0.43-\$ 1.04	\$ 0.90
Options outstanding at May 31, 2017	897,000	\$ 0.71-\$ 1.61	\$ 0.98
Options granted	287,000	\$ 2.41-\$3.90	\$ 3.63
Options exercised	(34,750)	\$ 0.71-\$ 1.04	\$ 0.80
Options canceled or expired	(10,625)	\$ 0.71-\$ 2.41	\$ 1.44
Options outstanding at May 31, 2018	1,138,625	\$ 0.71-\$ 3.90	\$ 1.65

The weighted average fair value of options granted during 2018 and 2017 was \$3.63 and \$1.55, respectively. The aggregate intrinsic value of options exercised during 2018 and 2017 was approximately \$87,000 and \$616,000, respectively. The aggregate intrinsic value of options outstanding at May 31, 2018 and 2017 was approximately \$2,755,000 and \$1,354,000, respectively. The aggregate intrinsic value of options vested and exercisable at May 31, 2018 and 2017 was approximately \$1,749,000 and \$616,000, respectively.

Activity as to non-vested stock options is as follows:

	STOCK OPTIONS
	WEIGHTED AVERAGE
	AVERAGE
	GRANT DATE
NUMBER OF SHARES	FAIR VALUE
Nonvested shares at May 31, 2017	
	517,250
\$	
	0.96
Granted	
	287,000
\$	
	3.63
Vested/Exercised	
	(212,125)
\$	
	1.00
Forfeited	

(9,125)

\$

1.56

Nonvested shares at May 31, 2018

583,000

\$

2.34

At May 31, 2018, total compensation cost related to non-vested stock option awards not yet recognized totaled approximately \$212,000. The weighted-average period over which this amount is expected to be recognized is 1.82 years. The weighted average remaining contractual term of options that were exercisable at May 31, 2018 was 5.25 years.

The following summarizes information about all of the Company's stock options outstanding at May 31, 2018. These options are comprised of those granted under the 1999, 2010, 2014 and 2017 plans.

WEIGHTED	WEIGHTED	NUMBER	NUMBER
AVERAGE	AVERAGE	EXERCISABLE	OUTSTANDING
REMAINING	EXERCISE	AT MAY 31,	05/31/2018
CONTRACTUAL	PRICE	2018	WEIGHTED
LIFE IN YEARS			AVERAGE
			EXERCISE PRICE
			RANGE OF
			EXERCISE PRICES
			\$ 0.71-\$ 0.84
			460,625
			4.66

\$0.80
371,750
\$0.79
\$ 0.85-\$ 1.04
65,000
2.22
\$0.99
32,625
\$0.98
\$ 1.20-\$ 1.61
330,000
8.32
\$1.26
151,250
\$1.23
\$ 2.41-\$ 3.90
283,000
8.69
\$3.65
--
--

## COMMON STOCK ACTIVITY

During the year ended May 31, 2018, options to purchase 34,750 shares of common stock were exercised at prices ranging from \$0.71 to \$1.04. Total proceeds to the Company were \$27,436.



During the year ended May 31, 2017, options to purchase 341,500 shares of common stock were exercised at prices ranging from \$0.43 to \$1.04. Total proceeds to the Company were \$157,728.

During the year ended May 31, 2018, the Company sold 342,088 shares of its common stock at prices ranging from \$3.73 to \$4.74 under its S-3 Registration Statement which resulted in gross proceeds of \$1,379,226 and net proceeds to the Company of \$1,275,933 (after receipt of subscriptions receivable at May 31, 2018) after deducting commissions for each sale and the initial legal and accounting fees related to the filing of the S-3. The subscriptions receivable of \$9,062 was collected on June 4, 2018.

FS - 15

---

**6. INCOME TAXES**

Income tax (expense) benefit from continuing operations for the years ended May 31, 2018 and 2017 consists of the following:

Years ended May 31,	2018	2017
Current:		
U.S. Federal	\$ --	\$ --
State and local	(800)	--
Total current	(800)	--
Deferred:		
U.S. Federal	(31,000)	--
State and local	--	--
Total deferred	(31,000)	--
Income tax (expense) benefit	\$ (31,800)	\$ --

Income tax benefit (expense) from continuing operations differs from the amounts computed by applying the U.S. Federal income tax rate applicable for each year (blended rate for 2018 (35% and 21%) and 35% for 2017) to pretax income as a result of the following:

Years ended May 31,	2018	2017
Computed "expected" tax benefit	\$ 418,258	\$ 317,997
Increase (reduction) in income taxes resulting from:		
Change in valuation allowance	(114,000)	(397,000)
State income taxes, net of federal benefit	71,794	30,215
Research and development tax credits	46,602	40,205
Permanent tax differences and other	78,795	8,583
Impact of tax rate changes	(533,249)	--
Income tax (expense)	\$ (31,800)	\$ --

The tax effect of significant temporary differences is presented below:

As of May 31,	2018	2017
Deferred tax assets:		
Accounts receivable, principally due to allowance for doubtful accounts and sales returns	\$ 15,000	\$ 19,000
Inventory valuation	13,000	14,000

Edgar Filing: BIOMERICA INC - Form 10-K

Compensated absences and deferred payroll	49,000	62,000
Net operating loss carryforwards	923,000	968,000
Tax credit carryforwards	385,000	307,000
Deferred rent expense	5,000	6,000
Other	163,000	108,000
Accumulated depreciation and amortization	6,000	--
Total deferred tax assets	1,559,000	1,484,000
Less valuation allowance	(1,549,000)	(1,435,000)
	10,000	49,000
Deferred tax liabilities:		
Accumulated depreciation of property and equipment	--	(8,000)
Net deferred tax asset	\$ 10,000	\$ 41,000

FS - 16

---

The Company has provided a valuation allowance of approximately \$1,549,000 and \$1,435,000 as of May 31, 2018 and 2017, respectively. The net change in the valuation allowance for the years ended May 31, 2018 and 2017 was an increase of approximately \$114,000 and \$397,000, respectively. The federal statutory tax rate of 35% has been changed to 21% for fiscal years beginning in 2019. Deferred tax assets as of May 31, 2018 have been adjusted to reflect the change in tax rates.

At May 31, 2018, the Company has federal income tax net operating loss carryforwards of approximately \$4,565,000. The federal net operating loss carryforwards begin to expire in 2030. At May 31, 2018, the Company has California state income tax net operating loss carryforwards of approximately \$2,918,000.

At May 31, 2018, the Company has federal research and development tax credit carryforward of approximately \$323,000. The federal credits begin to expire in 2027. The Company also had similar credit carryforwards for state purposes of \$62,000 at May 31, 2018.

Pursuant to Internal Revenue Code 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 Code, the annual use of the Company's NOLs would be limited if there is a cumulative change of ownership (as that term is defined in Section 382(g) of the Code) of greater than 50% in a three year period. Based on management's analysis the Company does not believe that a cumulative change in ownership of greater than 50% has taken place.

For the year ended May 31, 2018, the Company did an analysis of its ASC 740 position and has not identified any uncertain tax positions as defined under ASC 740. Should such position be identified in the future and should the Company owe interest and penalties as a result of this, these would be recognized as interest expense and other expense, respectively, in the consolidated financial statements. The Company is no longer subject to any significant U.S. federal tax examinations by tax authorities for years before fiscal year 2013.

At May 31, 2018, the Company has German net operating loss carryforwards from its foreign subsidiary of approximately \$35,000, resulting in a deferred tax asset of \$10,000. No valuation allowance has been established for the German deferred tax asset.

## **7. BUSINESS SEGMENTS**

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

Years ended May 31,	2018	2017
Net sales:		
Europe	\$ 2,023,000	\$ 2,238,000
United States	685,000	874,000
Asia	2,506,000	2,412,000
South America	214,000	65,000
Middle East	132,000	186,000
Other foreign	4,000	17,000
Total net sales	\$ 5,564,000	\$ 5,792,000

## 8. COMMITMENTS AND CONTINGENCIES

### OPERATING LEASES

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

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

The following is a schedule of rent payments due under the terms of the leases:

Years ending May 31,	
2019	\$ 302,408
2020	311,782
2021	321,449
2022	112,299
2023	42,960
Thereafter	159,256
Total	\$ 1,250,154

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.

Total gross rent expense in the U.S. for fiscal 2018 and 2017 was \$268,550 and \$260,393, respectively. Rent expense for the Mexico facility for fiscal 2018 and 2017 was \$45,963 and \$44,986, respectively.

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 Internal Revenue Code 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, 2018.

## CONTRACTS

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 is included in cost of sales for the agreement for each of the years ended May 31, 2018 and 2017. Sales of products manufactured under these agreements comprise approximately 2.6% and 2.5% of total sales for the years ended May 31, 2018 and 2017, 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, Biomerica, Inc. ("Biomerica") entered into an Exclusive Marketing License Agreement Agreement with Celtis Pharm Co., Ltd., a medical company in the Republic of Korea (South Korea) ( Celtis ), that grants to Celtis an exclusive license to market Biomerica's new InFoods® IBS products ( IBS Products ). The IBS Products identify patient-specific trigger foods that exacerbate/alleviate IBS (Irritable Bowel Disease) symptoms. The Agreement only allows for Biomerica's IBS Products to be sold by Celtis in the Republic of Korea with a possibility of expansion of territory in the future upon mutually agreeable negotiations. The term of the agreement is for a period of five years plus an additional two year term for Korean FDA clearance and begins after Biomerica first receives final clearance for sale of the IBS Products in the United States. The agreement may be cancelled if Biomerica has not obtained final approval or clearance for sale of the IBS Products in the United States from the United States FDA on or before December 31, 2017, or another date mutually agreed upon in writing. 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. In September 2017, an agreement to extend the date for final approval or clearance for sale of the IBS Products in the United States from the United States FDA was signed to extend the date to December 31, 2019.

Celtis, at its sole cost and expense, must use its commercially reasonable good faith efforts to obtain Korean FDA approval or clearance of the IBS Products.

The terms of the Agreement provide up to \$1.25 million in exclusivity fees based on certain milestones including Biomerica's starting clinical trials in the United States, receipt of US FDA clearance and Celtis' first sales of IBS Products in Korea. Should Biomerica not receive US FDA clearance for the IBS Products, \$250,000 of the up-front exclusivity fee shall convert into Biomerica common stock at the price of \$3.00 per share for a total of 83,333 shares.

Additionally, the Agreement provides for royalty fees paid to Biomerica that are based on a percentage of net sales of the IBS Products in Korea. Minimum royalties in order to retain the exclusive South Korean license total \$7.25 million starting at Korean FDA approval or clearance, which in no case will be later than May 31, 2019, or a date mutually agreed upon in writing, and continue for five years or longer if Korean FDA approval is obtained earlier than May 31, 2019. In September 2017, an agreement to extend this date was signed extending the date until April 30, 2020. Biomerica will sell the IBS Products to Celtis at a cost plus mark-up basis.

On May 25, 2016, in connection with the Agreement, Biomerica, Inc. consummated a Stock Purchase Agreement with Celtis in which Celtis agreed to purchase 333,334 shares of Biomerica's common stock at the purchase price of \$3.00 per share for an aggregate purchase price of \$1,000,002 (the "Private Placement").

The shares were offered and sold in the Private Placement to Celtis, an accredited investor, without registration under the Securities Act of 1933, as amended (the "Securities Act"), or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act and Regulation S promulgated thereunder and in reliance on similar exemptions under applicable state laws.

In October 2016, the Company entered into a Clinical Trial Agreement with Vanderbilt University Medical Center for a Specimen Collection Study for H. pylori testing in patients with dyspepsia. The study began in calendar 2017 and the maximum budget for the study is estimated at \$85,000.

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 work started in October 2017 with charges for work performed being invoiced and paid monthly. In November 2017, Biomerica announced the enrollment of its first patient at the University of Southern California for the Company's Helicobacter Pylori test.



In November 2017, the Company entered into a Clinical Trial Agreement with the University of Michigan to perform an InFoods 24 Endpoint Determination Study. The Company will be invoiced monthly for work performed the previous month. The maximum budget for the study is \$181,015.

In January 2018, the Company entered into a Clinical Trial Agreement with Beth Israel Deaconess Medical Center for the purposes of conducting An Antibody Guided Restriction Trial Using Biomerica InFoods 24G Test in patients with a previous diagnosis of Irritable Bowel Syndrome (IBS) . The study began in the first quarter of fiscal 2019. The Company will be invoiced monthly for work performed the previous month. The total cost of the study is estimated to be approximately \$142,000.

In April 2018, the Company entered into a Clinical Trial Agreement with Guardian Angel Research Center for the purposes of conducting a Specimen Collection Study Protocol for h. Pylori Testing in Patients with Dyspepsia. The Company will be invoiced monthly for work performed the previous month. The maximum budget for the study is \$75,400.

## 9. SUBSEQUENT EVENTS

Subsequent to May 31, 2018, the Company sold 44,321 shares of its common stock at prices ranging from \$3.84 to \$4.16 under its S-3 Registration Statement which resulted in net proceeds to the Company of \$170,958, after deducting commissions for each sale.

In August 2018, the Korean Intellectual Property Office (KIPO) issued a Certificate of Patent covering Biomerica's compositions, devices and methods of IBS sensitivity testing (entitled "COMPOSITIONS, DEVICES, AND METHODS OF IBS SENSIVITY TESTING").

The patent specifically applies to Biomerica's InFoods® IBS product, which is currently in a clinical study in the U.S. This patent is the first for the InFoods® patent portfolio, providing patent protection for InFoods® IBS in Korea until November 13, 2035.

FS - 20