

BIOMERICA INC  
Form 10-K  
August 29, 2016

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-K**

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

**For The Fiscal Year Ended May 31, 2016**

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)

**OTC-BULLETIN BOARD**

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

Yes  No

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

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

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

Yes  No

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

Yes  No

Indicate by check mark 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.

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Large Accelerated Filer

Non-Accelerated Filer

Accelerated Filer

Smaller Reporting Company

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

Yes  No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter (based upon 5,967,045 shares held by non-affiliates and the closing price of \$0.90 per share for Common Stock in the over-the-counter market as of November 30, 2015): \$5,370,341

Indicate the number of shares outstanding of each of the registrant's common stock, par value \$0.08, outstanding as of August 29, 2016: 8,169,673

DOCUMENTS INCORPORATED BY REFERENCE: Part III contains information incorporated by reference to the Company's proxy statement for its 2016 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, 2016. 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" or "our") was incorporated in Delaware in September 1971 as Nuclear Medical Systems, Inc. The Company also has two wholly owned subsidiaries, Biomerica de Mexico, established for future use as a maquiladora 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, food intolerances, diabetes and esoteric tests. These diagnostic test products utilize immunoassay technology. Some of these products have not yet 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 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. Biomerica has established wholly owned subsidiaries in Mexico and Germany for future use. 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.

Biomerica is a well-established, medical diagnostics manufacturer and distributor, especially active in the Physicians Office and Clinical Lab space.

## **PRODUCTION**

Most of our diagnostic test kits are processed and 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. We sublease facilities from and subcontract with Lancer Orthodontics (a former subsidiary) ( Lancer ) to provide labor and other services. 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 pursuing the development of two tests for the gastrointestinal market. Our increase in research and development spending is due to our focus on these tests and 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, facilities and equipment as well as outside contract services. Consolidated research and development expenses incurred by Biomerica for the years ended May 31, 2016 and 2015 aggregated \$780,333 and \$733,640, respectively.

InFoods® is a new approach to the treatment of irritable bowel syndrome (IBS) a large market with a lot of space for better solutions. Our Company's GI focus has led us to the development of a diagnostic-guided therapy for treatment of all subtypes of IBS (IBS-C, IBS-D and IBS-M). Specifically, we are developing a patent-pending method that is designed to identify patient-specific foods, the avoidance of which could alleviate an individual's IBS symptoms. A point-of-care product is being developed to allow physicians to perform the test in-office using a finger stick blood sample and could provide new incremental revenues to a GI medical practice. A billable CPT code that can be used by both clinical labs and physicians' offices is available for InFoods® diagnostic products. The clinical lab product will be

the first product we plan to submit for regulatory clearance. The InFoods® product is unique in that it has no drug-type side effects.

We are planning to pursue a de novo 510(k) rather than a PMA (Premarket Approval Application). 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 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, 2016 and 2015, the Company had one distributor which accounted for –30.3% and 16.3%, respectively, of consolidated sales.



## **BACKLOG**

At May 31, 2016 and 2015, Biomerica had a backlog of approximately and \$386,000 and \$154,000, 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, 2016, two companies combined accounted for 25.3% of the purchases of raw materials. For the year ended May 31, 2015, one company accounted for 13.6% 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 license expires on November 19, 2016. 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 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 regulations 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.

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 | 2016                | 2015                |
|-------------------|---------------------|---------------------|
| Europe            | \$ 2,166,000/42.1 % | \$ 2,716,000/54.7 % |
| United States     | 995,000/19.4 %      | 1,042,000/21.0 %    |
| Asia              | 1,731,000/33.7 %    | 1,016,000/20.4 %    |
| S. America        | 67,000/1.3 %        | 21,000/0.4 %        |
| Middle East       | 180,000/3.5 %       | 143,000/2.9 %       |
| Other foreign     | 1,000/0.0 %         | 24,000/0.6 %        |
| Total Sales       | \$ 5,140,000/100 %  | \$ 4,962,000/100 %  |

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. 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 have also registered the tradename InFoods . 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 several patent applications with regard to new tests to identify possible triggers for causing specific symptoms.

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.

The Company has two royalty agreements in which it has obtained rights to manufacture and market certain products for the life of the products. Royalty expense of approximately \$24,000 and \$21,000 is included in cost of sales for these agreements for each of the years ended May 31, 2016 and 2015. Beginning in fiscal 2011, the supplier was only required to pay royalties for one of the products due to the fact that the company no longer provides materials to make the other product, which was part of the original agreement. Sales of products manufactured under these agreements comprise approximately 3.5% and 3.2% of total sales for the years ended May 31, 2016 and 2015, respectively. The Company may license other products or technology in the future as it deems necessary for conducting business.

## EMPLOYEES

As of May 31, 2016 and 2015, the Company employed 36 employees, respectively, one of whom is employed part-time in the United States. The following is a breakdown between departments:

|                           | 2016 | 2015 |
|---------------------------|------|------|
| Administrative            | 5    | 5    |
| Marketing & Sales         | 3    | 3    |
| Production and Operations | 28   | 28   |
| Total                     | 36   | 36   |

In addition, Biomerica contracts with Lancer for the services of 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

Although not required to disclose risk factors, Biomerica has chosen to inform users of its financial information about certain risks associated with the Company's operations below.

Distribution - Biomerica has entered into various exclusive and non-exclusive distribution agreements (the "Agreements") which generally specify territories of distribution. The Agreements range in term from one to five years. Biomerica may be dependent upon such distributors for the marketing and selling of its products worldwide during the terms of these agreements. Such distributors are generally obligated to sell specified minimum quantities of the Company's products to keep the exclusive, while non-exclusive distributors have no minimum purchase requirements. There can be no assurance of the volume of product sales that may be achieved by such distributors. The Company has several large distributors which account for a significant portion of its business. The Company terminated the agreement with one such distributor in fiscal 2013 due to certain proprietary disagreements however the Company replaced this last distributor with a new distributor. The loss of one of these distributors could adversely affect the Company's financial results.

Government Regulation - Biomerica's immunodiagnostic products are regulated in the United States as medical devices primarily by the FDA and as such, require regulatory clearance or approval prior to commercialization in the United States. Pursuant to the Food, Drug and Cosmetics Act, and the regulations promulgated thereunder, the FDA regulates, among other things, the clinical testing, manufacture, labeling, promotion, distribution, sale and use of medical devices in the United States. Failure of Biomerica to comply with applicable regulatory requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, the government's refusal to grant pre-market clearance or pre-market approval of devices, withdrawal of marketing approvals, and criminal prosecution. In addition, there is the possibility that new health care reform laws may have a negative impact on the Company's sales.



Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain registrations or approvals required by foreign countries may be longer or shorter than that required for FDA clearance or approval, and requirements for licensing may differ significantly from FDA requirements. There can be no assurance that Biomerica will be able to obtain regulatory clearances for its current or any future products in the United States or in foreign markets.

European Community - Biomerica is required to obtain certification in the European community to sell products in those countries. The certification requires Biomerica to maintain certain quality standards. Biomerica has been granted certification and undergoes annual audits to assure that the Company remains in compliance with regulations. There is no assurance that Biomerica will be able to retain its certification in the future. The loss of business or the ability to conduct business in Europe could materially adversely affect the results of the Company.

Risk of Product Liability - Testing, manufacturing and marketing of Biomerica's products entails risk of product liability. In addition, the Company may have unknown intellectual property risks associated with patent or trademark infringement of other companies as well as having other companies infringe on our intellectual property. Biomerica currently has product liability insurance. There can be no assurance, however, that Biomerica will be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect Biomerica against losses due to product liability. An inability to obtain sufficient insurance coverage could prevent or inhibit the commercialization of Biomerica's products. In addition, a product liability claim or recall could have a material adverse effect on the business or financial condition of the Company.

Hazardous Materials - Biomerica's manufacturing and research and development involves the controlled use of hazardous materials and chemicals. Although Biomerica believes that safety procedures for handling and disposing of such materials comply with the standards prescribed by state and Federal regulations, 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.

Common stock performance - The common stock of the Company is subject to fluctuations as a result of a variety of factors including, but not limited to, financial results, general economic conditions, fluctuations in sales volumes and expenses, competition, and our failure to generate new products. The loss of one or more employees in senior management could adversely impact the Company's stock value.

Raw Materials - The Company utilizes certain raw materials that are critical to its manufacturing processes and relies on a limited number of manufacturers of such materials. Should any of these materials become unavailable or extremely cost prohibitive the sales of the Company could be adversely affected.

Ability to Obtain Financing - Although the Company has been able to obtain financing in the past, there is no guarantee that the Company will be able to obtain financing that may be needed in the future.

Limited Trading - As of August 26, 2016, the Company's stock was 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.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

The Company leases its office facilities. At May 31, 2016, 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 expires on August 31, 2016. The Company has 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 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. The Company also leases approximately 7,000 square feet of floor space in Mexico on a month-to-month basis as well as a smaller unit 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, 2016      | \$ 2.90    | \$ 1.11 |
| February 28, 2016 | \$ 1.50    | \$ 0.85 |
| November 30, 2015 | \$ 0.95    | \$ 0.77 |
| August 31, 2015   | \$ 1.44    | \$ 0.72 |
| May 31, 2015      | \$ 1.01    | \$ 0.72 |
| February 28, 2015 | \$ 0.93    | \$ 0.81 |
| November 30, 2014 | \$ 1.00    | \$ 0.79 |
| August 31, 2014   | \$ 1.03    | \$ 0.81 |

As of May 31, 2016, the number of holders of record of Biomerica's common stock was approximately 844, 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 May 25, 2016, Biomerica, Inc. ("Biomerica" or the "Company") entered into an Exclusive Marketing License 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 Exclusive Marketing License 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.

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 Exclusive Marketing License 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 (in the mid-teens) 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.

Biomerica will sell the IBS Products to Celtis at a cost plus mark-up basis.

On May 25, 2016, in connection with the Exclusive Marketing License Agreement, Biomerica, Inc. consummated a Stock Purchase Agreement with Celtis Pharm Co., Ltd. ( Celtis ) of South Korea 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 ).

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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.

We did not purchase any of our shares of common stock or other securities during our fiscal year ended May 31, 2016.

The table below provides information relating to our equity compensation plans as of May 31, 2016:

| Securities | Number of Securities to Be | Compensation Plans           | Equity compensation | Securities<br>Remaining                           |
|------------|----------------------------|------------------------------|---------------------|---|
| Plan       | Issued Upon Exercise of    | Weighted-Average Exercise    |                     | Available for<br>Future Issuance                  |
| Category   | Outstanding Options        | Price of Outstanding Options |                     | Under<br>Compensation<br>Plans                    |
|            |                            |                              |                     | (Excluding those<br>Reflected in<br>First Column) |

Plans approved

by Securities holders

1,199,000

\$0.81

183,000

**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 \$5,139,816 for fiscal 2016 compared to \$4,962,373 for fiscal 2015. This represents an increase of \$177,443, or 3.6%. The sales increase was a result of increased sales in Asia of approximately \$715,000, which was offset primarily by decreased sales in Europe of approximately \$550,000 in Europe and \$47,000 in the U.S.

Consolidated cost of sales in fiscal 2016 as compared to fiscal 2015 increased from \$3,420,567 to \$3,615,774, or by \$195,207. The percentage of cost of sales relative to sales increased from 68.9 %, to 70.3%, due to various factors which included product mix of goods sold, higher wages and overall expenses.

Consolidated selling, general and administrative costs increased in fiscal 2016 as compared to fiscal 2015 from \$1,478,761 to \$1,570,661, or by \$91,900, or 6.2%. The increase was primarily a result of higher outside services and bad debt expense. Interest expense remained constant in fiscal 2016 at \$167 as compared to \$0 in fiscal 2015. Interest and dividend income increased from \$21,906 to \$24,123 due to higher dividends from the Company's investment in its Polish distributor.

Consolidated research and development expense was \$780,333 in fiscal 2016 as compared to \$733,640 in fiscal 2015. This is an increase of \$46,693, primarily as a result of increased costs related to the possible FDA clearance of new gastrointestinal products and feasibility for FDA clearance. See *Research and Development* for a more extensive description of the research being conducted.

The net loss increased from \$331,410 to \$1,499,787 primarily due to a one-time valuation allowance being established on the Company's deferred tax asset in the amount of \$703,800 as compared to a tax benefit in fiscal 2015 of \$298,000, which resulted in a difference between fiscal 2016 and 2015 of \$1,001,000 in one-time non-cash tax expense. Although management believes that it will be able to use deferred tax assets in the future, due to investment in research and development, which increased recent losses, a valuation allowance is required to be established.

Other income increased from \$2,255 to \$7,009, an increase of \$4,754.

## **LIQUIDITY AND CAPITAL RESOURCES**

As of May 31, 2016, the Company had cash and cash equivalents in the amount of \$1,888,925 as compared to \$1,088,307 of cash and cash equivalents as of May 31, 2015. As of May 31, 2016 and 2015, the Company had working capital of \$4,329,041 and \$3,867,668, respectively.

### *Operating Activities*

During fiscal 2016, cash used in operating activities was \$208,782 as compared to \$405,481 in fiscal 2015. The decrease in cash used of \$208,782 in fiscal 2016 was primarily due to the collection of \$151,159 of accounts receivable, inventory used of \$137,131 and a pre-tax loss of \$795,987, as compared to a collection of accounts receivable totaling \$348,667 in fiscal 2015, offset by an increase in inventories of \$243,378 and a pre-tax loss of \$646,434.

*Investing Activities*

During fiscal 2016, cash used in investing activities was \$95,192 as compared to \$22,782 in fiscal 2015. Cash of \$91,556 and \$10,503 was utilized for the purchase of property and equipment in fiscal 2016 and 2015, respectively. In fiscal 2016, the Company invested \$3,636 into licenses for new products and product registration fees as compared to \$14,179 in fiscal 2015.

*Financing Activities*

Cash provided by financing activities in fiscal 2016 was \$1,105,914 as compared to \$9,560 in fiscal 2015. In fiscal 2016 the Company realized \$995,978 of net proceeds from the sale of restricted common stock.

At May 31, 2016, in accordance with ASC 740, the Company created a valuation allowance for all of its deferred tax assets. This resulted in a one-time non-cash charge to income tax expense of \$1,038,000 and a reduction in the short and long-term deferred tax assets.

## **OFF BALANCE SHEET ITEMS**

There were no off-balance sheet arrangements as of May 31, 2016.

## **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. 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 should establish a valuation allowance of \$1,038,000, which resulted in a reduction of our deferred tax asset to \$41,000.

## **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, 2016, 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 quarter 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, 2016, 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 2016 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, 2016.

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

This information is incorporated by reference to the Company's proxy statement for its 2016 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, 2016.

**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 2016 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, 2016.

**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 2016 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, 2016.

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

Please refer to the Company's proxy statement for its 2016 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, 2016.

## 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.

#### Exhibit No. Description

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

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- Certificate of Amendment of Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on December 20, 1994 (incorporated by reference to Exhibit 3.7 filed with Registrant's Annual Report on Form 10-KSB for the fiscal year ended May 31, 1995).
- 3.8 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.
- 10.3 1999 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 March 29, 2000 and on May 30, 2007).
- 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).
- 23.1 Consent of Independent Registered Public Accounting Firm (PKF).
- 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: 8/29/16

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

Date: 8/29/16

Zackary S. Irani  
Director, Chief Executive Officer

/s/ Janet Moore

Date: 8/29/16

Janet Moore,

Secretary, Director, Chief Financial  
Officer

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

Date: 8/29/16

Francis R. Cano, Ph.D.

Director, Audit Committee Member

/s/ Allen Barbieri

Date: 8/29/16

Allen Barbieri

Director, Audit Committee Member

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

Date: 8/29/16

Jane Emerson, M.D., Ph.D

Director, Audit Committee Member



**BIOMERICA, INC. AND SUBSIDIARIES**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders

Biomerica, Inc. and Subsidiaries

Irvine, California

We have audited the accompanying consolidated balance sheets of Biomerica, Inc. (a Delaware Corporation) and Subsidiaries (the "Company") as of May 31, 2016 and 2015 and the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for each of the two years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We have conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal controls over financial reporting. Our audits included consideration of internal controls over financial reporting as a basis for designing audit procedures that are appropriate in the circumstance, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Biomerica, Inc. and Subsidiaries as of May 31, 2016 and 2015, and the results of its consolidated operations and cash flows for each of the two years then ended in conformity with accounting principles generally accepted in the United States of America.

August 29, 2016  
San Diego, California

/s/ PKF  
PKF  
Certified Public Accountants  
A Professional Corporation

**BIOMERICA, INC. AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS**

May 31,

2016

May 31,

2015

ASSETS

CURRENT ASSETS:

Cash and cash  
equivalents

\$

1,888,925

\$

1,088,307

Accounts receivable, less  
allowance for doubtful

accounts of \$8,405 and  
\$17,468, respectively

969,474

1,111,570

Inventories, net

1,863,091

2,027,372

Prepaid expenses and  
other

113,578

164,352

Total current assets

4,835,068

4,391,601

PROPERTY AND  
EQUIPMENT

Equipment

1,496,119

1,442,856

Furniture, fixtures and  
leasehold improvements

308,440

270,147

Total property and  
equipment

1,804,559

1,713,003

Accumulated  
depreciation

(1,423,900)

(1,267,617)

Net property and  
equipment

380,659

445,386

DEFERRED TAX  
ASSETS

41,000

744,000

INTANGIBLE ASSETS,  
net

248,801

321,304

INVESTMENTS

165,324

165,324

OTHER ASSETS

55,653

56,838

TOTAL ASSETS

\$

5,726,505

\$

6,124,453

LIABILITIES AND  
SHAREHOLDERS'  
EQUITY

CURRENT  
LIABILITIES

Accounts payable and  
accrued expenses

\$

333,485

\$



392,139

Accrued compensation

172,542

131,794

Total current liabilities

506,027

523,933

COMMITMENTS AND  
CONTINGENCIES  
(NOTE 9)

SHAREHOLDERS'  
EQUITY

Preferred stock, no par value, 5,000,000 authorized shares, no shares issued and outstanding at May 31, 2016 and 2015

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--

Common stock, \$.08 par value; 25,000,000 shares authorized; 8,169,673 and 7,566,714 shares issued and outstanding, respectively

653,573

605,336

Additional paid-in capital

19,399,720

18,326,890

Accumulated other comprehensive loss

(13,586)

(12,264)

Accumulated deficit

(14,819,229)

(13,319,442)

Total shareholders' equity

5,220,478

5,600,520

TOTAL LIABILITIES  
AND  
SHAREHOLDERS'  
EQUITY

\$

5,726,505

\$

6,124,453

See accompanying notes  
to consolidated financial  
statements.

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

| FOR THE YEARS ENDED MAY 31  | 2016                  | 2015                |
|---|-----------------------|---------------------|
| Net sales   | \$ 5,139,816          | \$ 4,962,373        |
| Cost of sales   | (3,615,774)           | (3,420,567)         |
| <b>GROSS PROFIT</b>   | <b>1,524,042</b>      | <b>1,541,806</b>    |
| <b>OPERATING EXPENSES</b>   |                       |                     |
| Selling, general and administrative                                   | 1,570,661             | 1,478,761           |
| Research and development  | 780,333               | 733,640             |
| Total operating expenses  | 2,350,994             | 2,212,401           |
| <b>LOSS FROM OPERATIONS</b>   | <b>(826,952)</b>      | <b>(670,595)</b>    |
| <b>OTHER INCOME (EXPENSE)</b>   |                       |                     |
| Interest expense  | (167)                 | -                   |
| Interest and dividend income  | 24,123                | 21,906              |
| Other income  | 7,009                 | 2,255               |
| Total other income  | 30,965                | 24,161              |
| <b>LOSS BEFORE INCOME TAXES</b>                                       | <b>(795,987)</b>      | <b>(646,434)</b>    |
| <b>INCOME TAX (EXPENSE) BENEFIT</b>                                   | <b>(703,800)</b>      | <b>315,024</b>      |
| <b>NET LOSS</b>   | <b>\$ (1,499,787)</b> | <b>\$ (331,410)</b> |
| <b>BASIC NET LOSS PER COMMON SHARE</b>                                | <b>\$ (.20)</b>       | <b>\$ (0.04)</b>    |
| <b>DILUTED NET LOSS PER COMMON SHARE</b>                              | <b>\$ (.20)</b>       | <b>\$ (0.04)</b>    |
| <b>WEIGHTED AVERAGE NUMBER OF COMMON AND COMMON EQUIVALENT SHARES</b> |                       |                     |
| Basic   | 7,626,078             | 7,552,262           |
| Diluted   | 7,626,078             | 7,552,262           |
| <b>NET LOSS</b>   | <b>\$ (1,499,787)</b> | <b>\$ (331,410)</b> |
| <b>OTHER COMPREHENSIVE LOSS</b>                                       |                       |                     |
| Foreign currency translation  | (1,322)               | (2,115)             |
| <b>COMPREHENSIVE LOSS</b>   | <b>\$ (1,501,109)</b> | <b>\$ (333,525)</b> |

See accompanying notes to consolidated financial statements.



**BIOMERICA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**YEARS ENDED MAY 31, 2016 AND 2015**

| Common<br>Stock | Accumulated<br>Additional<br>Other<br>Paid-in<br>Comprehensive<br>Capital Loss | Accumulated<br>Deficit | Shares           |
|-----------------|--|------------------------|------------------|
|                 |  |                        | Amount           |
|                 |  |                        | Total            |
|                 |  | Balances, May 31, 2014 | 7,543,714        |
|                 |  |                        | \$<br>603,496    |
|                 |  |                        | \$<br>18,309,154 |

|                           |              |
|---------------------------|--------------|
|                           | \$           |
|                           | (10,149)     |
|                           | \$           |
|                           | (12,988,032) |
|                           | \$           |
|                           | 5,914,469    |
| Exercise of stock options |              |
|                           | 23,000       |
|                           | 1,840        |
|                           | 7,720        |
|                           | --           |
|                           | --           |
|                           | 9,560        |
|                           | 55           |

Foreign currency translation

--

--

--

(2,115)

--

(2,115)

Compensation expense in connection with options granted

--

--

10,016



|                        |           |
|------------------------|-----------|
|                        | --        |
|                        | --        |
|                        | 10,016    |
| Net loss               | --        |
|                        | --        |
|                        | --        |
|                        | --        |
|                        | --        |
|                        | (331,410) |
|                        | (331,410) |
| Balances, May 31, 2015 |           |

7,566,714

605,336

18,326,890

(12,264)

(13,319,442)

5,600,520

Exercise of stock options

269,625

21,570

88,366

|                              |         |
|------------------------------|---------|
|                              | --      |
|                              | --      |
|                              | 109,936 |
| Foreign currency translation | --      |
|                              | --      |
|                              | --      |
|                              | (1,322) |
|                              | --      |
|                              | (1,322) |
| Private Placement            | 333,334 |

26,667

969,311

--

--

995,978

Compensation expense in connection with options granted

--

--

15,153

--

60

|          |             |
|----------|-------------|
|          | --          |
|          | 15,153      |
| Net loss | --          |
|          | --          |
|          | --          |
|          | --          |
|          | --          |
|          | (1,499,787) |
|          | (1,499,787) |

Balances, May 31, 2016

8,169,673

\$

653,573

\$

19,399,720

\$

(13,586)

\$

(14,819,229)

\$

5,220,478

See accompanying notes to consolidated financial statements.

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

| For the Years Ended May 31,   | 2016           | 2015         |
|---|----------------|--------------|
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>                                 |                |              |
| Net loss  | \$ (1,499,787) | \$ (331,410) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                |              |
| Depreciation and amortization   | 232,422        | 253,275      |
| Change in provision for allowance for doubtful accounts                     | (9,063)        | (12,532)     |
| Inventory reserve   | 27,150         | (18,222)     |
| Gain on disposal of property and equipment                                  | --             | (665)        |
| Stock option expense  | 15,153         | 10,016       |
| Decrease in deferred rent liability   | (28,073)       | (20,406)     |
| Decrease (increase) in deferred tax assets                                  | 703,000        | (298,000)    |
| Changes in assets and liabilities:  |                |              |
| Accounts receivable   | 151,159        | 348,667      |
| Inventories   | 137,131        | (243,378)    |
| Prepaid expenses and other  | 50,774         | (60,780)     |
| Other assets  | 1,185          | (20,541)     |
| Accounts payable and accrued expenses                                       | (30,581)       | (29,136)     |
| Accrued compensation  | 40,748         | 17,631       |
| Net cash used in operating activities                                       | (208,782)      | (405,481)    |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>                                 |                |              |
| Purchases of property and equipment   | (91,556)       | (10,503)     |
| Purchases of intangible assets  | (3,636)        | (14,179)     |
| Proceeds from sales of property and equipment                               | --             | 1,900        |
| Net cash used in investing activities                                       | (95,192)       | (22,782)     |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                |                |              |
| Proceeds from sale of common stock  | 995,978        | --           |
| Proceeds from exercise of stock options                                     | 109,936        | 9,560        |
| Net cash provided by financing activities                                   | 1,105,914      | 9,560        |
| Effect of exchange rate changes on cash                                     | (1,322)        | (2,115)      |
| Net increase (decrease) in cash and cash equivalents                        | 800,618        | (420,818)    |
| CASH AND CASH EQUIVALENTS, beginning of year                                | 1,088,307      | 1,509,125    |
| CASH AND CASH EQUIVALENTS, end of year                                      | \$ 1,888,925   | \$ 1,088,307 |

**SUPPLEMENTAL DISCLOSURE OF CASH-FLOW INFORMATION**

Cash paid during the period for:

|              |        |        |
|--------------|--------|--------|
| Interest     | \$ 167 | \$ 138 |
| Income taxes | \$ 800 | \$ 800 |

See accompanying notes to consolidated financial statements





**BIOMERICA, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**YEARS ENDED MAY 31, 2016 AND 2015**

**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, 2016 and 2015 include the accounts of Biomerica, Inc. ("Biomerica") as well as its German subsidiary and Mexican subsidiary. The Mexican subsidiary has not begun operations. 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. 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, 2016 and 2015, the Company had one distributor which accounted for 30.3% and 16.3%, respectively, of consolidated sales. The Company performs ongoing credit evaluations of its customers and requires prepayment in some circumstances. At May 31, 2016, two customers accounted for 60.3% of gross accounts receivable. At May 31, 2015, two customers accounted for 53.0 % of gross accounts receivable.

For the year ended May 31, 2016, two companies accounted for 25.3% of the purchases of raw materials. For the year ended May 31, 2015, one company accounted for 13.6 % of the purchases of raw materials.

## **GEOGRAPHIC CONCENTRATION**

As of May 31, 2016 and 2015, approximately \$659,000 and \$530,000 of Biomerica's gross inventory and approximately \$26,000 and \$35,000, 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.

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 market. 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:

|                   | 2016         | 2015         |
|-------------------|--------------|--------------|
| Raw materials     | \$ 942,000   | \$ 958,000   |
| Work in progress  | 690,000      | 831,000      |
| Finished products | 231,000      | 238,000      |
| Total             | \$ 1,863,000 | \$ 2,027,000 |

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. For the years ended May 31, 2016 and 2015 inventory reserves were approximately \$52,000 and \$25,000, 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 and leasehold improvements amounted to \$156,283 and \$178,219 for the years ended May 31, 2016 and 2015, 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 and purchased technology use rights, and 17 years for patents. Amortization amounted to \$76,139 and \$75,056 for the years ended May 31, 2016 and 2015, respectively. Intangible assets with indefinite lives such as perpetual licenses are not amortized but rather tested for impairment at least annually.

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 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, 2016.

## 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 to be less 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.

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**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 valuation model that uses assumptions for expected volatility, expected dividends, expected forfeiture rate, expected term, and the risk-free interest rate. Expected volatilities are based on weighted averages of the historical volatility of the Company's 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 are as follows:

|                         | 2016            | 2015           |
|-------------------------|-----------------|----------------|
| Dividend yield          | 0%              | 0%             |
| Expected volatility     | 51.77-55.29%    | 49.53 -62.68%  |
| Risk free interest rate | 1.55-1.75%      | 1.26 -1.67%    |
| Expected life           | 3.75-6.25 years | 3.75-6.0 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. An allowance is established when necessary for estimated returns as revenue is recognized. As of May 31, 2016 and 2015, the allowance for returns is \$0.

**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 \$780,333 and \$733,640 of research and development expenses during the years ended May 31, 2016 and 2015, 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 liabilities, 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, 2016, in accordance with ASC 740, the Company created a valuation allowance for all of its deferred tax assets. This resulted in a one-time charge to income tax expense of approximately \$1,038,000 and a reduction in the short and long-term deferred tax assets.

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 \$2,000 and \$6,000 for the years ended May 31, 2016 and 2015, respectively.

## **FOREIGN CURRENCY TRANSLATION**

The subsidiary located in Germany operates primarily using local functional currency. Accordingly, assets and liabilities of this subsidiary are translated using exchange rates in effect at the end of the period, and revenues and costs are translated using average exchange rates for the period. The subsidiary in Mexico, although not operating, has two bank accounts which according to exchange rates in effect at the end of each period need to be adjusted for that fluctuation. The resulting adjustments are presented as a separate component of accumulated other comprehensive loss.

## **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 options not included in the loss per share calculation for the years ended May 31, 2016 and 2015 were 1,199,000 and 1,148,000 respectively.

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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                                | 2016           | 2015         |
|---|----------------|--------------|
| Numerator for basic and diluted net loss per common share | \$ (1,499,787) | \$ (331,410) |
| Denominator for basic net loss per common share           | 7,626,078      | 7,552,262    |
| Effect of dilutive securities:                            |                |              |
| Options   | --             | --           |
| Denominator for diluted net loss per common share         | 7,626,078      | 7,552,262    |
| Basic net loss per common share                           | \$ (0.20)      | \$ (0.04)    |
| Diluted net loss per common share                         | \$ (0.20)      | \$ (0.04)    |

## 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 February 2013, the FASB issued ASU No. 2013-04, *Liabilities (Topic 405): Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation Is Fixed at the Reporting Date* (ASU 2013-04). The amendments in ASU 2013-04 provide guidance for the recognition, measurement, and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation within the scope of this update is fixed at the reporting date, except for obligations addressed within existing guidance in GAAP. The guidance requires an entity to measure those obligations as the sum of the amount the reporting entity

agreed to pay on the basis of its arrangement among its co-obligors and any additional amount the reporting entity expects to pay on behalf of its co-obligors. The guidance in this update also requires an entity to disclose the nature and amount of the obligation as well as other information about those obligations. The amendments in this standard are effective retrospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, which corresponded to the Company's first quarter of fiscal 2015. The adoption of ASU 2013-04 did not have a material impact on the Company's consolidated financial statements.

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 No. 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 US GAAP 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 is evaluating the provisions of this statement and has not determined what impact the adoption of ASU 2015-11 will have on the Company's financial position or results of operations.

On November 20, 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes* ( *ASU-2015-17* ). The update eliminates the requirement to classify deferred tax assets and liabilities on a classified statement of financial position. ASU 2015-17 is effective for fiscal years beginning after December 15, 2015, and interim periods within those annual periods. Early adoption is permitted for financial statements as of the beginning of an interim or annual reporting period. The Company chose to adopt ASU 2015-17 as of the fiscal quarter ended November 30, 2015.

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-S016-09 will take effect for public companies for the annual periods beginning after December 15, 2016. Management is evaluating the provisions of this statement and has not determined what impact the adoption of ASU-2016-09 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.

## **RECLASSIFICATION**

The Company reclassified the Deferred Tax Asset reported in the prior fiscal year under Current Assets to present the Deferred Tax Asset as non-current in accordance with ASU 2015-17.

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**3. INTANGIBLE ASSETS, NET**

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

|                               | 2016       |    | 2015      |
|-------------------------------|------------|----|-----------|
| Patents and licenses          | \$ 509,485 | \$ | 505,849   |
| Less accumulated amortization | (260,684)  |    | (184,545) |
|                               | \$ 248,801 | \$ | 321,304   |

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

|            |  |    |         |
|------------|--|----|---------|
| 2017       |  | \$ | 73,418  |
| 2018       |  |    | 70,108  |
| 2019       |  |    | 64,149  |
| 2020       |  |    | 21,138  |
| 2021       |  |    | 12,181  |
| Thereafter |  |    | 7,807   |
| Total      |  | \$ | 248,801 |

**4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

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

|                  | 2016       |    | 2015    |
|------------------|------------|----|---------|
| Accounts payable | \$ 325,984 | \$ | 356,565 |
| Deferred rent    | 7,501      |    | 35,574  |
|                  | \$ 333,485 | \$ | 392,139 |

**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.

Activity as to stock options outstanding are as follows:

|                                     | NUMBER OF     | PRICE RANGE    | WEIGHTED |
|-------------------------------------|---------------|----------------|----------|
|                                     | STOCK OPTIONS | PER SHARE      | AVERAGE  |
|                                     |               | EXERCISE PRICE |          |
| Options outstanding at May 31, 2014 | 860,500       | \$0.38-\$0.84  | \$0.51   |
| Options granted                     | 356,000       | \$0.82-\$0.85  | \$0.82   |
| Options exercised                   | (23,000)      | \$0.38-\$0.71  | \$0.42   |
| Options canceled or expired         | (45,500)      | \$0.43-\$0.85  | \$0.72   |
| Options outstanding at May 31, 2015 | 1,148,000     | \$0.38-\$0.85  | \$0.60   |
| Options granted                     | 345,000       | \$1.04-\$1.20  | \$1.17   |
| Options exercised                   | (269,625)     | \$0.38-\$0.84  | \$0.41   |
| Options canceled or expired         | (24,375)      | \$0.43-\$1.04  | \$0.74   |
| Options outstanding at May 31, 2016 | 1,199,000     | \$0.43-\$1.20  | \$0.81   |

The weighted average fair value of options granted during 2016 and 2015 was \$1.17 and \$0.82, respectively. The aggregate intrinsic value of options exercised during 2016 and 2015 was approximately \$256,000 and \$11,000 respectively. The aggregate intrinsic value of options outstanding at May 31, 2016 and 2015 was approximately \$952,000 and \$376,000, respectively. The aggregate intrinsic value of options vested and exercisable at May 31, 2016 and 2015 was approximately \$542,000 and \$284,000, respectively.

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

STOCK  
OPTIONS

WEIGHTED  
AVERAGE

|                                 | AVERAGE<br>GRANT DATE<br>FAIR VALUE |
|---------------------------------|-------------------------------------|
| NUMBER OF<br>SHARES             |                                     |
| Nonvested shares at May 31,2015 |                                     |
|                                 | 527,125                             |
| \$                              |                                     |
|                                 | 0.75                                |
| Granted                         |                                     |
|                                 | 345,000                             |
| \$                              |                                     |
|                                 | 1.17                                |
| Vested/Issued                   |                                     |
|                                 | (179,250)                           |
| \$                              |                                     |
|                                 | 0.66                                |
| Forfeited                       |                                     |
|                                 | (19,625)                            |
| \$                              |                                     |
|                                 | 0.77                                |
| Nonvested shares at May 31,2016 |                                     |

673,250

\$

0.99

At May 31, 2016, total compensation cost related to non-vested stock option awards not yet recognized totaled approximately \$63,000. The weighted-average period over which this amount is expected to be recognized is 3.18 years. The weighted average remaining contractual term of options that were exercisable at May 31, 2016 was 2.27 years.

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The following summarizes information about all of the Company's stock options outstanding at May 31, 2016. These options are comprised of those granted under the 1999, 2010 and 2014 plans.

| WEIGHTED<br>AVERAGE<br>REMAINING<br>CONTRACTUAL<br>LIFE IN YEARS | WEIGHTED<br>AVERAGE<br>EXERCISE<br>PRICE | NUMBER<br>EXERCISABLE<br>AT MAY 31,<br>2016 | NUMBER<br>OUTSTANDING<br>05/31/2016<br>WEIGHTED<br>AVERAGE<br>EXERCISE PRICE<br>RANGE OF<br>EXERCISE PRICES |
|--|--|---|---|
|  |  |   | \$0.43  |
|  |  |   | 311,750   |
|  |  |   | 0.61  |
|  |  |   | \$0.43  |
|  |  |   | 311,750   |
|  |  |   | \$0.43  |
|  |  |   | \$ 0.71 - \$ 0.85   |
|  |  |   | 545,250   |
|  |  |   | 4.23  |
|  |  |   | \$0.79  |
|  |  |   | 214,000   |
|  |  |   | \$0.76  |
|  |  |   | \$ 1.04 - \$ 1.20   |
|  |  |   | 342,000   |

8.59

\$1.17

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**STOCK ACTIVITY**

During the fiscal year ended May 31, 2015, options to purchase 23,000 shares of common stock were exercised at prices ranging from \$0.38 to \$0.71. Total proceeds to the Company were \$9,560.

During the fiscal year ended May 31, 2016, options to purchase 269,625 shares of common stock were exercised at prices ranging from \$0.38 to \$0.84. Total proceeds to the Company were \$109,936.

During the fiscal year ended May 31, 2016, the Company sold 333,334 shares of its common stock at a price of \$3.00 per share for net proceeds of \$995,978.

**6. INCOME TAXES**

Income tax (expense) benefit from continuing operations for the years ended May 31, 2016 and 2015 consists of the following:

|                              | 2016         | 2015       |
|------------------------------|--------------|------------|
| Current:                     |              |            |
| U.S. Federal                 | \$ --        | \$ --      |
| State and local              | (800)        | 17,024     |
| Total current                | (800)        | 17,024     |
| Deferred:                    |              |            |
| U.S. Federal                 | (579,414)    | 267,418    |
| State and local              | (123,586)    | 30,582     |
| Total deferred               | (703,000)    | 298,000    |
| Income tax (expense) benefit | \$ (703,800) | \$ 315,024 |

Income tax benefit (expense) from continuing operations differs from the amounts computed by applying the U.S.

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Federal income tax rate of 35 percent to pretax income as a result of the following:

| Years ended May 31,                                  | 2016         | 2015       |
|--|--------------|------------|
| Computed "expected" tax benefit                      | \$ 274,479   | \$ 226,024 |
| Increase (reduction) in income taxes resulting from: |              |            |
| Change in valuation allowance                        | (1,038,000)  | --         |
| State income taxes, net of federal benefit           | 34,276       | 27,000     |
| Research and development tax credits                 | 21,844       | 63,000     |
| Permanent tax differences and other                  | 3,601        | (1,000)    |
| Income tax (expense) (benefit)                       | \$ (703,800) | \$ 315,024 |

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The tax effect of significant temporary differences is presented below:

| Years ended May 31,   | 2016        | 2015       |
|---|-------------|------------|
| Deferred tax assets:  |             |            |
| Accounts receivable, principally due to allowance for doubtful accounts and sales returns | \$ 3,000    | \$ 7,000   |
| Inventory valuation   | 11,000      | 9,000      |
| Compensated absences and deferred payroll   | 60,000      | 45,000     |
| Net operating loss carryforwards  | 705,000     | 484,000    |
| Tax credit carryforwards  | 268,000     | 239,000    |
| Deferred rent expense   | 3,000       | 13,000     |
| Other   | 82,000      | 56,000     |
| Total deferred tax assets   | 1,132,000   | 853,000    |
| Less valuation allowance  | (1,038,000) | --         |
|   | 94,000      | 853,000    |
| Deferred tax liabilities:   |             |            |
| Accumulated depreciation of property and equipment  | (53,000)    | (109,000)  |
| Net deferred tax asset  | \$ 41,000   | \$ 744,000 |

The Company has provided a valuation allowance of approximately \$1,038,000 and \$0 as of May 31, 2016 and 2015, respectively. The net change in the valuation allowance for the years ended May 31, 2016 and 2015 was an increase of approximately \$1,038,000 and \$0, respectively.

At May 31, 2016 and 2015, the Company has federal income tax net operating loss carryforwards of approximately \$2,247,000 and \$1,445,000 respectively. Of the reported net operating loss carryforwards, approximately \$467,000 are related to windfall tax benefits from the exercise of the Company's stock options by certain employees. Pursuant to ASC 718, the federal benefit of approximately \$163,000 associated with this portion of the net operating loss will be credited to additional paid-in capital when the tax benefits are actually realized. The federal net operating loss carryforwards begin to expire in 2030. At May 31, 2016 and 2015, the Company has California state income tax net operating loss carryforwards of approximately \$1,417,000 and \$913,000, respectively.

At May 31, 2016, the Company has federal research and development tax credit carryforward of approximately \$233,000. The federal credits begin to expire in 2027. The Company also had similar credit carryforwards for state purposes of \$35,000 at May 31, 2016.

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 fiscal year ended May 31, 2016 and 2015, 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 2012.

**7. BUSINESS SEGMENTS**

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

|                 | 2016         | 2015         |
|-----------------|--------------|--------------|
| Net sales:      |              |              |
| Europe          | \$ 2,166,000 | \$ 2,716,000 |
| United States   | 995,000      | 1,042,000    |
| Asia            | 1,731,000    | 1,016,000    |
| South America   | 67,000       | 21,000       |
| Middle East     | 180,000      | 143,000      |
| Other foreign   | 1,000        | 24,000       |
| Total net sales | \$ 5,140,000 | \$ 4,962,000 |

**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 ends 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 is \$21,000 per month, increasing to \$23,637 through August 31, 2021. The security deposit of \$22,080 remains the same. The following is a schedule of rent payments due under the terms of the lease extension:

|                      |              |
|----------------------|--------------|
| Years Ending May 31, |              |
| 2016                 | \$ 255,240   |
| 2017                 | 257,670      |
| 2018                 | 265,401      |
| 2019                 | 273,369      |
| 2020                 | 281,577      |
| 2021                 | 70,911       |
| Total                | \$ 1,404,168 |

According to the terms of the lease, 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 2016 and 2015 was \$235,927 and \$236,154, respectively. Rent expense for the Mexico facility for fiscal 2016 and 2015 was \$36,234 and \$36,000 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, 2016.

## **CONTRACTS**

The Company has two royalty agreements in which it has obtained rights to manufacture and market certain products for the life of the products. Royalty expense of approximately \$24,000 is included in cost of sales for these agreements for each of the years ended May 31, 2016 and 2015. Beginning in fiscal 2011 the Company is only required to pay royalties for one of the products due to the fact that the company that was paid the royalties no longer provides materials to make that product, which was part of the original agreement. Sales of products manufactured under these agreements comprise approximately 3.5% and 3.2 % of total sales for the years ended May 31, 2016 and 2015, respectively. The Company may license other products or technology in the future as it deems necessary for conducting business.

On May 25, 2016, Biomerica, Inc. ("Biomerica" or the "Company") entered into an Exclusive Marketing License 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 Exclusive Marketing License 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.

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 Exclusive Marketing License 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.

Biomerica will sell the IBS Products to Celtis at a cost plus mark-up basis.

On May 25, 2016, in connection with the Exclusive Marketing License Agreement, Biomerica, Inc. consummated a Stock Purchase Agreement with Celtis Pharm Co., Ltd. ( Celtis ) of South Korea 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.

The Company has other royalty agreements, however they are not considered material.

## **9. SUBSEQUENT EVENTS**

On July 14, 2016 the Board of Directors of the Company voted to expand its board of directors from five to six members and voted to elect Dr. Mark Sirgo to fill the vacant position. A non-qualified stock option to purchase 35,000 shares of the Company's common stock was granted to Dr. Sirgo at the time he joined the Board of Directors. The option was granted at an exercise price of \$1.52, is exercisable 25% on July 14, 2017 and then 25% each year thereafter. The option will expire July 14, 2026.

On June 3, 2016 the Company granted a non-qualified option to purchase 20,000 shares of Biomerica common stock to a consultant. The option was granted at an exercise price of \$1.61, is exercisable 25% on June 3, 2017 and then 25% each year thereafter. The option expires June 3, 2021.

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.

