

BIOMERICA INC  
Form 10-K  
August 29, 2012

**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, 2012**

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**

(State or other jurisdiction of

Incorporation of organization)

**95-2645573**

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

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

(Address of principal executive offices)

**92614**

(Zip Code)

REGISTRANT'S TELEPHONE NUMBER:

**(949) 645-2111**

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

**None**

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

(Title of each class)

(Name of each exchange on which registered)

**COMMON STOCK, PAR VALUE \$0.08**

**OTC-BULLETIN BOARD**

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

Yes [ ] No [X]

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 [X] 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 [X] 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 S-T (paragraph 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to

submit and post such files).

Yes  No

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

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

|                          |   |
|--------------------------|---|
| Large Accelerated Filer  | Accelerated Filer <input type="checkbox"/>                    |
| <input type="checkbox"/> |   |
| Non-Accelerated Filer    | Smaller Reporting Company <input checked="" type="checkbox"/> |
| <input type="checkbox"/> |   |

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 the last business day of the registrant's most recently completed second fiscal quarter (based upon 5,290,147 shares held by non-affiliates and the closing price of \$0.48 per share for Common Stock in the over-the-counter market as of November 30, 2011): \$2,539,271.

Indicate the number of shares outstanding of each of the registrant's common stock, par value \$0.08, outstanding as of August 29, 2012: 6,952,339

**DOCUMENTS INCORPORATED BY REFERENCE:** Part III contains information incorporated by reference to the Company's proxy statement for its 2012 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, 2012. 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 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.

Our clinical laboratory diagnostic products include tests for bone and anemia conditions, gastrointestinal diseases, food intolerance, diabetes and others. These diagnostic test kits utilize enzyme immunoassay technology. Some of these products have not yet been submitted for clearance by the *Food and Drug Administration* ("FDA") for diagnostic use, but can be sold in various foreign countries.

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 and 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. During July 2010 the Company eliminated its dedicated research and development department in an effort to follow its current strategy of licensing more developed technology from other companies, universities and institutions. The Company expended considerable funds in the effort to ready certain new products for market (both internally developed and licensed from others). The Company plans to continue to license technology from other institutions in order to increase its product line and bring new products to market at a faster pace. The Company utilizes 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.

## **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) 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 regulations. In June 2008 the Company incorporated in Mexico under the name of Biomerica de Mexico for the purpose of establishing our own maquiladora operation in Mexico at some time in the future.

Manufacturing operations are regulated by the FDA Good Manufacturing Practices for medical devices. We have an internal Quality Control 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**

Biomerica was engaged in research and development to broaden its diagnostic product line in specific areas. However, in July 2010 the Company eliminated its internal research group (two scientists) in favor of licensing in new technology from outside institutions in order to more rapidly expand its product offerings and decrease its time to market. The Company has continued to incur development costs (which are classified under “Research and Development”) utilizing technical personnel in an effort to complete the development of its newly licensed products. The Company also utilizes technical personnel to conduct other development activities, 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, facilities and equipment as well as outside contract services. Consolidated research and development expenses incurred by Biomerica for the years ended May 31, 2012 and 2011 aggregated \$347,128 and \$420,571, respectively.

## **MARKETS AND METHODS OF DISTRIBUTION**

Biomerica has approximately 450 current customers for its diagnostic business, of which approximately 100 are 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 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). Marketing plans are utilized in targeting each of the two markets.

For the years ended May 31, 2012 and 2011 the Company had one customer which accounted for 37.2% and 22.2%, respectively, of consolidated sales.

## **BACKLOG**

At May 31, 2012 and 2011 Biomerica had a backlog of approximately \$742,000 and \$256,000, 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 years ended May 31, 2012 and 2011, two and zero vendors, respectively, accounted for more than 10% of the consolidated purchases of raw materials.

The 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 medical devices. As a result, we are considered to be a medical device manufacturer, and as such are subject to the regulations of numerous governmental entities. These agencies include the Food and Drug Administration (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 and 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 notification 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. The following is a breakdown of the Biomerica products by class:

Class I - Fortel™ Ovulation test, EZ-LH™ Rapid Ovulation test, Fortel Microalbumin test, Campylobacter Elisa Kit, E. coli O157 Elisa Kit (Class I Exempt), Verotoxin Elisa Kit (Class I Exempt) and C. difficile Elisa Kit.

Class II - GAP™ IgG H. Pylori ELISA kit, GAP™ IgM H. Pylori ELISA kit, PTH (intact) ELISA kit, Calcitonin ELISA kit, Erythropoietin ELISA kit, ACTH ELISA kit, Isletest™ GAD ELISA kit, IAA ELISA kit, GAP™ IgA H. Pylori ELISA kit, Myoglobin ELISA, Troponin I ELISA, HS-CRP ELISA, Allerquant™ Food Intolerance Kits, Allerquant™ Food Additive Intolerance Kit, Intrinsic Factor Autoantibodies ELISA Kit, LKM-1 Autoantibodies IgG ELISA Kit, Calprotectin ELISA Kit, Cryptosporidium ELISA Kit, Giardia ELISA Kit, E. histolytica ELISA Kit, Anti-Gliadin IgG ELISA Kit, Anti-Gliadin IgA ELISA Kit, and Transglutaminase ELISA , Fortel™ Ultra Midstream (OTC and plastic stick), EZ-HCG™ Rapid Pregnancy test (professional and dipstick), EZ Detect™ Fecal Occult Blood test (Physician's dispenser pack and OTC), Aware™ Breast Self-Examination Pad, drugs of abuse rapid tests, EZ-HP Professional, EZ-HP OTC, Fortel™ Cat Allergy Test, Fortel™ Dog Allergy Test, Fortel™ Dust Mite Allergy Test, FSH, H. Pylori antigen, Listeria Salmonella and Shigella rapid tests;

Class III - Isletest™ ICA ELISA kit, TPMT ELISA Kit, and EZ-PSA (Professional and OTC).

If the FDA finds that the device is not substantially equivalent to a predicate device, the device may be deemed a Class III device, and a manufacturer or seller is required to file a Pre-Market Approval ("PMA") application. Approval of a PMA application for a new medical device usually requires, among other things, extensive clinical data on the safety and effectiveness of the device. PMA applications may take years to be approved after they are filed, but approval is required before the product can be sold for general use in the U.S. In addition to requiring clearance or approval for new medical devices, FDA rules also require a new 510(k) filing and review period, prior to marketing a changed or modified version of an existing legally marketed device, if such changes or modifications could significantly affect the safety or effectiveness of that device. The FDA prohibits the advertisement or promotion of any approved or cleared device for uses other than those that are stated in the device's approved or cleared application.

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 Quality System Requirements, 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, 2012. 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 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 such countries. We believe that our international sales to date have been in compliance with the laws of all the foreign countries in which we have made sales. Exports of most medical devices are also subject to certain FDA regulatory controls.



The following products are FDA-cleared and may be sold to clinical laboratories, physician laboratories and/or retail outlets in the United States as well as internationally:

ACTH ELISA Kit

AWARE™ Breast Self-Examination Kit

Calcitonin ELISA Kit

Drugs-of-Abuse Rapid Tests

Erythropoietin ELISA Kit

EZ-HCG™ Rapid Pregnancy Test

EZ-LH™ Rapid Ovulation Test

EZ Detect™ Fecal Occult Blood Test (Physician's package, OTC package)

GAP™ IgG H.Pylori ELISA Kit

hs-CRP ELISA

Myoglobin ELISA

PTH (Intact) ELISA Kit

Troponin I ELISA

The following products are not FDA-cleared. These are sold internationally and can be sold in the U.S. "FOR RESEARCH ONLY":

Allerquant™ IgG Food Intolerance ELISA Kit (90-foods, 14-foods, custom kits)

Allerquant™ IgG Food Additives Kit

EZ-PSA™ Rapid Test

EZ-H. Pylori™ Rapid Test

Fortel™ Cat Allergy Test

Fortel™ Dog Allergy Test

Fortel™ Microalbumin Test

Fortel™ Ultra Midstream Pregnancy Test

Fortel™ Ovulation Test

H. pylori Antigen Test

Listeria Rapid Test

Shigella Rapid Test

Salmonella Rapid Test

GAP™ IgM H. Pylori ELISA Kit

GAP™ IgA H. Pylori ELISA Kit

Gliadin IgG ELISA Kit

Gliadin IgA ELISA Kit

Transglutaminase IgA ELISA Kit

Isletest™ GAD ELISA Kit

Isletest™ ICA ELISA Kit

Isletest™ IAA ELISA Kit

Intrinsic Factor Autoantibodies ELISA Kit

LKM-1 Autoantibodies IgG ELISA Kit

Campylobacter ELISA Kit

Cryptosporidium ELISA Kit

E. coli O157 ELISA Kit

Giardia ELISA Kit

Verotoxin ELISA Kit

C. difficile Antibody ELISA Kit

E. histolytica ELISA Kit

TPMT ELISA Kit

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 March 2006. 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 regulations.

Biomerica's Quality Management System is in compliance with the International Standards Organization (ISO) 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 | 2012               | 2011                |
|-------------------|--------------------|---------------------|
| Europe            | \$ 2,533,000/41.7% | \$ 2,483,000/50.7 % |
| United States     | 1,074,000/17.7%    | 1,160,000/23.7 %    |
| Asia              | 2,420,000/39.8%    | 1,153,000/23.5 %    |
| S. America        | 2,000/ 0.03%       | 28,000/ 0.6 %       |
| Middle East       | 22,000/ 0.3%       | 45,000/ 0.9 %       |
| Other foreign     | 30,000/ 0.5%       | 30,000/ 0.6 %       |
| Total Revenues    | \$ 6,081,000/100%  | \$ 4,899,000/100 %  |

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 60 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**

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We registered the tradenames "Fortel", "Isletest", and "GAP" with the Office of Patents and Trademarks on December 31, 1985. 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. In addition, Biomerica holds the following patents: Immunotherapy Agents for Treatment of IgE Mediated Allergies and Allergen-thymic Hormone Conjugates for Treatment of IgE Mediated Allergies, U.S. Patent #5,275,814, issued January 4, 1994 and Diagnostic Test for Measuring Islet Cell Autoantibodies and Reagents Relating Thereto, U.S. Patent #5,786,221, issued July 28, 1998. 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.

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.



On March 27, 2009 the Company signed an Asset Purchase Agreement with a European company for the purchase of certain technology related to the manufacture of certain medical diagnostic tests. Consideration for this purchase was a nominal deposit upon signing the agreement and a nominal transfer fee upon successful commencement of production of the products. A royalty shall be paid for five years beginning on the date of first sale of finished product derived from the purchased assets. Royalty expense for this license was approximately \$5,500 and \$6,000 for the years ended May 31, 2012 and 2011, respectively.

In October 2009, the Company entered into a non-exclusive, worldwide, perpetual, irrevocable, and transferable cross-license agreement to acquire technology and intellectual property from and make available its technology and intellectual property related to enzyme-linked immunosorbent assay products to be marketed by the Company. Pursuant to the terms of the license agreement, the Company has paid \$25,000 for the license for six products, with a similar amount to be paid for one additional product if it is transferred. The Company will be amortizing the costs for these licenses over a ten year period. As part of this agreement, the Company must pay royalties on future sales of these products between 4% and 8% and is eligible to receive royalties from certain of its products licensed in the same percentages. The Company accrues this royalty when it becomes payable. The Company incurred approximately \$16,500 and \$3,750 in licensing fees during fiscal 2012 and 2011, respectively.

In May 2010, the Company acquired from an inventor the exclusive, perpetual license to a United States patent applicable to the measurement of thiopurine methyltransferase within patients prior to commencing treatment with thiopurine drugs. The product is currently being redeveloped by the Company. Pursuant to the terms of the license agreement, the Company was granted an exclusive, worldwide, perpetual license to manufacture, market, distribute and sell the products contemplated by the patents subject to the payment of \$25,000 as reimbursement to the patent holder for legal and other costs associated with obtaining the patent, which was paid in June 2010. The Company is amortizing the initial cost of \$25,000 for this license over a ten year period. As of May 31, 2012 the Company has amortized \$5,000 of this. As part of this agreement, the Company must pay royalties on future sales of these products between 4% and 8% through September 30, 2022. The agreement also has minimum escalating royalty payments which must be made for the Company to keep its exclusivity for the license. The Company accrues this royalty when it becomes payable. Royalty in the amounts of \$10,294 and \$0 was recorded for the years ended May 31, 2012 and 2011.

On October 19, 2010, the Company signed an agreement with a University to acquire the rights to manufacture and market certain products using two patents owned by the University. The Company paid a license issue fee of \$15,000 initially and will pay royalties on net sales quarterly. The Company has amortized approximately \$12,300 of this licensing fee as of May 31, 2012. Royalty expense for this license was approximately \$8,000 and \$4,000 for the years ended May 31, 2012 and 2011, respectively.

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 \$30,000 and \$57,000 is included in cost of sales for these agreements for the years ended May 31, 2012 and 2011, respectively. Beginning in fiscal 2011, the Company 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 3.4% and 7.2% of total sales for the years ended May 31, 2012 and 2011, respectively. The Company may license other products or technology in the future as it deems necessary for conducting this line of business.

**EMPLOYEES**

As of May 31, 2012 and 2011, the Company employed 33 and 28, respectively, 1 of whom, is a part-time employee in the United States. The following is a breakdown between departments:

|                           | 2012 | 2011 |
|---------------------------|------|------|
| Administrative            | 4    | 4    |
| Marketing & Sales         | 3    | 3    |
| Production and Operations | 26   | 21   |
| Total                     | 33   | 28   |

In addition, Biomerica contracts with Lancer for the services of 14 people at its Mexican 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 risk 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 not obligated to sell any specified minimum quantities of the Company's product 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 (one of whom accounts for approximately 37.2% and 22.2% of our total sales, respectively, in fiscal 2012 and 2011) which account for a significant portion of its business. 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 Federal Food, Drug and Cosmetic 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.

**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. 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.

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 effected.

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 - The Company is traded on the Over-the-Counter stock market. Trading on this exchange 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, 2012, the Company had approximately 22,000 square feet of floor space at its corporate headquarters at 17571 Von Karman Avenue in Irvine, California, 92614 since 2009. The lease for its headquarters expires on August 31, 2016. The Company also leases approximately 7,000 square feet of floor space in Mexico on a month-to-month basis.

#### **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 has been quoted on the OTC Bulletin Board under the symbol "BMRA.OB". 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, 2012      | \$         | 0.89 | \$  | 0.60 |
| February 28, 2012 | \$         | 0.76 | \$  | 0.43 |
| November 30, 2011 | \$         | 0.48 | \$  | 0.42 |
| August 31, 2011   | \$         | 0.47 | \$  | 0.38 |
| May 31, 2011      | \$         | 0.48 | \$  | 0.41 |
| February 29, 2011 | \$         | 0.49 | \$  | 0.34 |
| November 30, 2010 | \$         | 0.45 | \$  | 0.39 |
| August 31, 2010   | \$         | 0.47 | \$  | 0.38 |

As of May 31, 2012, the number of holders of record of Biomerica's common stock was approximately 861, 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.



We did not issue any equity securities that were not registered under the Securities Act during our fiscal year ended May 31, 2012.

We did not purchase any of our shares of common stock or other securities during our fiscal year ended May 31, 2012.

The table below provides information relating to our equity compensation plans as of May 31, 2012:

| Securities<br>Plan<br>Category                                 | Number of Securities to Be<br>Issued Upon Exercise of<br>Outstanding Options | Compensation Plans<br>Weighted-Average Exercise<br>Price of Outstanding Options | Securities Remaining<br>Available for Future Issuance<br>Under Compensation Plans<br>(Excluding those Reflected<br>in<br>First Column) |
|--|--|---|--|
| Equity compensation<br>Plans approved by<br>Securities holders | 1,004,500  | \$0.46  | 148,500  |

#### 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 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 material 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.

## RESULTS OF OPERATIONS

Our consolidated net sales were \$6,081,131 for fiscal 2012 compared to \$4,899,375 for fiscal 2011. This represents an increase of \$1,181,756, or 24.1%. The increase was primarily due to increased sales in Asia.

Cost of sales in fiscal 2012 as compared to fiscal 2011 increased from \$3,373,786 to \$3,783,955 or by \$410,169. The percentage of cost of sales relative to sales decreased from 68.9% to 62.2%, or by 6.7%, due to various factors including our benefit of having higher sales while having certain fixed expenses which limited the increase in cost of sales. At May 31, 2011, the Company had accrued in other liabilities approximately \$59,100 of expenses related to free product (which was shipped in the first quarter of fiscal 2012) due a large distributor for sales incentives, which contributed to a 1.2% increase in cost of goods as a percentage of sales in fiscal 2011.

Selling, general and administrative costs increased in fiscal 2012 as compared to fiscal 2011 from \$1,237,279 to \$1,445,049, or by \$207,770 (16.8%). The increase was primarily a result of higher stock based compensation expense, bonus expense, licensing amortization in fiscal 2012 and a credit in fiscal 2011 of approximately \$80,000 for the reduction of accrued vacation due to the former CEO's estate.

Research and development expense was \$347,128 in fiscal 2012 as compared to \$420,571 in fiscal 2011. This is a decrease of \$73,443 (17.5%). The Company had larger expenses in fiscal 2011 related to the discontinuance of the dedicated research department and associated severance costs incurred. No such costs were incurred in fiscal 2012.

Interest expense decreased from \$5,830 to \$1,585 in fiscal 2012 as compared to fiscal 2011, or \$4,245 (72.8%). The change in interest expense resulted from decreased balances pertaining to the equipment loan. Interest and dividend income increased from \$7,367 to \$8,347 due to higher cash balances.

Other income decreased from \$290,170 to \$101,688, a decrease of \$188,482. Most of the decrease in other income in fiscal 2012 as compared to 2011 was a result of receiving a grant under the Qualifying Therapeutic Discovery Project in fiscal 2011 versus insurance proceeds received in fiscal 2012, as discussed under Liquidity and Capital Resources below.

## **LIQUIDITY AND CAPITAL RESOURCES**

As of May 31, 2012, the Company had cash and cash equivalents in the amount of \$1,077,342, as compared to \$989,270 of cash and cash equivalents as of May 31, 2011. As of May 31, 2012 and 2011, the Company had working capital of \$3,894,342 and \$3,261,418 respectively.

### *Operating Activities*

During 2012, cash provided by operations was \$147,412 as compared to \$328,803 in fiscal 2011. The decrease in fiscal 2012 was primarily due to an increase in accounts receivable of \$534,428 during fiscal year ended May 31, 2012 as compared to a decrease in accounts receivable of \$261,769 in fiscal 2011 along with changes in certain non-cash items.

*Investing Activities*

During fiscal 2012, cash used in investing activities was \$113,170 as compared to \$431,683 in fiscal 2011. Cash of \$164,798 and \$141,084 was utilized for the purchase of property and equipment in fiscal 2012 and 2011, respectively. In addition, in fiscal 2011 the Company invested \$165,324 in a distributor of its products as compared to zero in fiscal 2012. In addition, in fiscal 2012, the Company received approximately \$102,000 as insurance proceeds from water damages sustained (see below). In fiscal 2012 the Company invested \$50,000 to license new products as compared to \$125,275 in fiscal 2011.

*Financing Activities*

Cash provided by financing activities in fiscal 2012 was \$55,400 as compared to cash provided by financing activities of \$37,891 in fiscal 2011. The increase was primarily due to borrowings on the line of credit and pay downs on an equipment loan.

*Other*

During the quarter ended February 29, 2012, the Company experienced water damage from a burst pipe. Expenses of \$33,522 were incurred as a result of this. Property and equipment amounting to \$68,106 were purchased to replace damaged, fully depreciated equipment and fixtures. The Company's insurance company reimbursed the Company \$101,628, which covered approximately all of its expenses plus cost of replacement property and equipment. The net gain is reflected under other income and (expense) as gain from insurance proceeds.

On February 13, 2009, the Company entered into a Small Business Banking Agreement with Union Bank for a one year business line of credit (the "Line") in the amount of \$400,000. The interest rate for the line of credit was the prime rate in effect on the first day of the billing period, as published in the Wall Street Journal Prime West Coast Edition, plus a spread of 1.00%. Minimum monthly payments will be the sum of (i) the amount of interest charge for the billing period, plus (ii) any amount past due, plus (iii) any fees, late charges and/or out-of-pocket expenses assessed. If the Line is not renewed as of the last day of the term of the Line, the entire unpaid balance of the Line, including unpaid fees and charges will be due and payable. The Company has granted the bank security interest in the assets of the Company as collateral. The Company has renewed this line each year. The Line expires February 24, 2013. The Company owed \$43,000 on this Line as of May 31, 2012.

**OFF BALANCE SHEETS ITEMS**

There were no off-balance sheet arrangements as of May 31, 2012.

## **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 describes the significant accounting policies essential to the consolidated financial statements. The preparation of these 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 share-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 share-based compensation expense.

Historically we were in a loss position for tax purposes, and established a valuation allowance against deferred tax assets, as we did not believe it was likely that we would generate sufficient taxable income in future periods to realize the benefit of our deferred tax assets. Because the Company has not achieved net income consistently over the previous five fiscal years, predicting future taxable income is difficult, and requires the use of significant judgment. Due to the fact that many factors can influence profitability, management determined at May 31, 2012, that \$392,000 of its deferred tax asset should be reserved for. Management has determined that the tax asset of \$238,000 as of May 31, 2012 is an appropriate estimate of the Company's utilization of its deferred tax assets. Management will re-evaluate this determination periodically.

## **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 are not meant to be an exhaustive discussion of risks that apply to companies such as Biomerica, Inc. Like other businesses, Biomerica, Inc. is susceptible to macroeconomic downturns in the United States or abroad, as were experienced in recently, that may affect the general economic climate and performance of Biomerica, Inc. 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; 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 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 Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective at the "reasonable assurance" level. Based on that evaluation the Chief Executive Officer and



Chief Financial Officer 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 Chief Executive Officer and Chief Financial Officer, 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 Chief Executive Officer and Chief Financial Officer concluded that, as of May 31, 2012, 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 generally accepted accounting principles.

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 generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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 Chief Executive Officer and the Chief Financial Officer, 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. Based on this assessment, management, with the participation of the Chief Executive Officer and Chief Financial Officer, believes that, as of May 31, 2012, 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 2012 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, 2012.

**ITEM 11. EXECUTIVE COMPENSATION**

This information is incorporated by reference to the Company's proxy statement for its 2012 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, 2012.

**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 2012 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, 2012.

**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 2012 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, 2012.

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

Please refer to the Company's proxy statement for its 2012 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, 2012.

## **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). |

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- 3.5 Certificate of Amendment of Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on November 4, 1987 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
- 3.6 Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).
- 3.7 Certificate of Amendment of Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on December 20, 1994 (incorporated by reference to Exhibit 3.7 filed with Registrant's Annual Report on Form 10-KSB for the fiscal year ended May 31, 1995).
- 3.8 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).
- 10.31 2010 Stock Incentive Plan of Registrant (incorporated by reference to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on February 9, 2012.)
- 10.39 Small Business Banking Agreement (Business Line of Credit Number 0366422012) with Union Bank (incorporated by reference to the Company's February 28, 2009 Form 10Q filed April 14, 2009).
- 10.4 Small Business Banking Agreement (Business Loan Number 0366422020) with Union Bank (incorporated by reference to the Company's February 28, 2009 Form 10Q filed April 14, 2009).23.1
- 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.

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|         |  |
|---------|--|
| 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.  |
| 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: 8/29/12

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

Signature and Capacity

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

Date: 8/29/12

/s/ Janet Moore  
Janet Moore,  
Secretary, Director, Chief Financial Officer

Date: 8/29/12

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

Date: 8/29/12

/s/ Allen Barbieri  
Allen Barbieri  
Director

Date: 8/29/12

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

Date: 8/29/12



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

**BIOMERICA, INC. AND SUBSIDIARIES**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders

Biomerica, Inc. and Subsidiaries

Irvine, California

We have audited the accompanying consolidated balance sheets of Biomerica, Inc. (a Delaware Corporation) and Subsidiaries as of May 31, 2012 and 2011 and the related consolidated statements of operations and comprehensive income (loss), shareholders' equity, and cash flows for the years ended May 31, 2012 and 2011. 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, 2012 and 2011, and the results of its consolidated operations and cash flows for the years ended May 31, 2012 and 2011 in conformity with accounting principles generally accepted in the United States of America.

August 29, 2012  
San Diego, California

/s/ PKF  
Certified Public Accountants  
A Professional Corporation

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

|  | May 31, 2012        | May 31, 2011        |
|--|---------------------|---------------------|
| <b>ASSETS</b>  |                     |                     |
| <b>CURRENT ASSETS:</b>   |                     |                     |
| Cash and cash equivalents  | \$ 1,077,342        | \$ 989,270          |
| Accounts receivable, less allowance for doubtful accounts<br>of \$113,191 and \$32,204, respectively                     | 1,200,516           | 747,075             |
| Inventories, net   | 1,821,072           | 1,785,525           |
| Deferred tax assets, current portion   | 177,000             | 127,000             |
| Prepaid expenses and other   | 210,700             | 237,563             |
| <b>Total current assets</b>  | <b>4,486,630</b>    | <b>3,886,433</b>    |
| <b>PROPERTY AND EQUIPMENT</b>  |                     |                     |
| Equipment  | 1,185,098           | 1,065,145           |
| Furniture, fixtures and leasehold improvements   | 244,410             | 214,353             |
| <b>Total property and equipment</b>  | <b>1,429,508</b>    | <b>1,279,498</b>    |
| Accumulated depreciation   | (844,684)           | (712,175)           |
| <b>Net property and equipment</b>  | <b>584,824</b>      | <b>567,323</b>      |
| <b>DEFERRED TAX ASSETS, net of current portion</b>   | <b>61,000</b>       | <b>111,000</b>      |
| <b>INTANGIBLE ASSETS, net</b>  | <b>194,583</b>      | <b>177,410</b>      |
| <b>INVESTMENTS</b>   | <b>165,324</b>      | <b>165,324</b>      |
| <b>OTHER ASSETS</b>  | <b>78,561</b>       | <b>47,888</b>       |
| <b>TOTAL ASSETS</b>  | <b>\$ 5,570,922</b> | <b>\$ 4,955,378</b> |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>  |                     |                     |
| <b>CURRENT LIABILITIES</b>   |                     |                     |
| Accounts payable and accrued expenses  | \$ 362,447          | \$ 451,569          |
| Accrued compensation   | 186,841             | 138,056             |
| Line of credit   | 43,000              | --                  |
| Loan for equipment purchase  | --                  | 35,390              |
| <b>Total current liabilities</b>   | <b>592,288</b>      | <b>625,015</b>      |
| <b>COMMITMENTS AND CONTINGENCIES</b>   |                     |                     |
| <b>SHAREHOLDERS' EQUITY</b>  |                     |                     |
| Preferred stock, no par value, 5,000,000 authorized shares, no shares issued<br>and outstanding at May 31, 2012 and 2011 | --                  | --                  |
|  | 556,186             | 549,466             |

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Common stock, \$.08 par value; 25,000,000 shares authorized; 6,952,339 and 6,868,339 shares issued and outstanding, respectively

|  |              |              |
|--|--------------|--------------|
| Additional paid-in capital                 | 17,737,807   | 17,643,121   |
| Accumulated other comprehensive loss       | (6,030)      | (4,460)      |
| Accumulated deficit                        | (13,309,329) | (13,857,764) |
| Total shareholders' equity                 | 4,978,634    | 4,330,363    |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | \$ 5,570,922 | \$ 4,955,378 |

See accompanying notes to consolidated financial statements.

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

| YEARS ENDED MAY 31  | 2012              | 2011              |
|---|-------------------|-------------------|
| Net sales   | \$ 6,081,131      | \$ 4,899,375      |
| Cost of sales   | (3,783,955)       | (3,373,786)       |
| <b>GROSS PROFIT</b>   | <b>2,297,176</b>  | <b>1,525,589</b>  |
| <b>OPERATING EXPENSES</b>   |                   |                   |
| Selling, general and administrative                                       | 1,445,049         | 1,237,279         |
| Research and development  | 347,128           | 420,571           |
| Total operating expenses  | 1,792,177         | 1,657,850         |
| <b>INCOME (LOSS) FROM OPERATIONS</b>                                      | <b>504,999</b>    | <b>(132,261)</b>  |
| <b>OTHER INCOME (EXPENSE)</b>   |                   |                   |
| Interest expense  | (1,585)           | (5,830)           |
| Interest and dividend income  | 8,347             | 7,367             |
| Other income  | 101,688           | 290,170           |
| Total other income  | 108,450           | 291,707           |
| <b>INCOME BEFORE INCOME TAXES</b>   | <b>613,449</b>    | <b>159,446</b>    |
| <b>INCOME TAX EXPENSE</b>   | <b>(65,014)</b>   | <b>(1,999)</b>    |
| <b>NET INCOME</b>   | <b>\$ 548,435</b> | <b>\$ 157,447</b> |
| <b>BASIC NET INCOME PER COMMON SHARE</b>                                  | <b>\$ 0.08</b>    | <b>\$ 0.02</b>    |
| <b>DILUTED NET INCOME PER COMMON SHARE</b>                                | <b>\$ 0.08</b>    | <b>\$ 0.02</b>    |
| <b>WEIGHTED AVERAGE NUMBER OF COMMON AND<br/>COMMON EQUIVALENT SHARES</b> |                   |                   |
| Basic   | 6,887,929         | 6,668,229         |
| Diluted   | 7,107,759         | 6,704,307         |
| <b>NET INCOME</b>   | <b>\$ 548,435</b> | <b>\$ 157,447</b> |

OTHER COMPREHENSIVE LOSS

|                              |         |       |
|------------------------------|---------|-------|
| Foreign currency translation | (1,570) | (947) |
|------------------------------|---------|-------|

|                      |            |            |
|----------------------|------------|------------|
| COMPREHENSIVE INCOME | \$ 546,865 | \$ 156,500 |
|----------------------|------------|------------|

See accompanying notes to consolidated financial statements.

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

|  | Common Stock |            | Additional<br>Paid-in<br>Capital | Other<br>Comprehensive<br>Loss | Accumulated<br>Deficit | Total        |
|--|--------------|------------|----------------------------------|--------------------------------|------------------------|--------------|
|  | Shares       | Amount     |                                  |                                |                        |              |
| Balances, May 31,<br>2010  | 6,660,839    | \$ 532,866 | \$17,548,754                     | \$ (3,513)                     | \$(14,015,211)         | \$ 4,062,896 |
| Exercise of stock<br>options                                     | 207,500      | 16,600     | 66,400                           | --                             | --                     | 83,000       |
| Foreign currency<br>translation                                  | --           | --         | --                               | (947)                          | --                     | (947)        |
| Compensation<br>expense in connection<br>with options granted    | --           | --         | 27,967                           | --                             | --                     | 27,967       |
| Net income   | --           | --         | --                               | --                             | 157,447                | 157,447      |
| Balances, May 31,<br>2011  | 6,868,339    | 549,466    | 17,643,121                       | (4,460)                        | (13,857,764)           | 4,330,363    |
| Exercise of stock<br>options and warrants                        | 84,000       | 6,720      | 41,070                           | --                             | --                     | 47,790       |
| Foreign currency<br>translation                                  | --           | --         | --                               | (1,570)                        | --                     | (1,570)      |
| Compensation<br>expense in<br>connection with<br>options granted | --           | --         | 53,616                           | --                             | --                     | 53,616       |
| Net income   | --           | --         | --                               | --                             | 548,435                | 548,435      |
| Balances, May 31,<br>2012  | 6,952,339    | \$ 556,186 | \$17,737,807                     | \$ (6,030)                     | \$(13,309,329)         | \$ 4,978,634 |

See accompanying notes to consolidated financial statements.





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

| For the Years Ended May 31,  | 2012       | 2011       |
|--|------------|------------|
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>  |            |            |
| Net income   | \$ 548,435 | \$ 157,447 |
| Adjustments to reconcile net income<br>to net cash provided by operating activities: |            |            |
| Depreciation and amortization  | 180,124    | 147,810    |
| Change in provision for losses on accounts receivable                                | 80,987     | 8,998      |
| Inventory reserve  | (7,841)    | 1,227      |
| (Gain) loss on disposal of property and equipment                                    | (101,628)  | 5,942      |
| Stock option expense   | 53,616     | 27,967     |
| Write off of license-related intangible asset  | --         | 13,982     |
| Increase in deferred rent liability  | 1,338      | 8,238      |
| Gain on settlement of vacation accrual   | --         | (80,605)   |
| Changes in assets and liabilities:   |            |            |
| Accounts receivable  | (534,428)  | 261,769    |
| Inventories  | (27,706)   | 3,815      |
| Prepaid expenses and other   | 26,863     | (49,860)   |
| Other assets   | (30,673)   | 31,886     |
| Accounts payable and other accrued expenses  | (90,460)   | (121,757)  |
| Accrued compensation   | 48,785     | (88,056)   |
| Net cash provided by operating activities  | 147,412    | 328,803    |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>  |            |            |
| Investment in distributor  | --         | (165,324)  |
| Purchases of property and equipment  | (164,798)  | (141,084)  |
| Purchases of intangible assets   | (50,000)   | (125,275)  |
| Proceeds from insurance claim  | 101,628    | --         |
| Net cash used in investing activities  | (113,170)  | (431,683)  |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>   |            |            |
| Net borrowings on line of credit   | 43,000     | --         |
| Proceeds from exercise of stock options and warrants                                 | 47,790     | 83,000     |
| Payments on loan for equipment purchase  | (35,390)   | (45,109)   |
| Net cash provided by financing activities  | 55,400     | 37,891     |
| Effect of exchange rate changes on cash  | (1,570)    | (947)      |
| Net increase (decrease) in cash and cash equivalents                                 | 88,072     | (65,936)   |

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|  |              |            |
|--|--------------|------------|
| CASH AND CASH EQUIVALENTS, beginning of year | 989,270      | 1,055,206  |
| CASH AND CASH EQUIVALENTS, end of year       | \$ 1,077,342 | \$ 989,270 |

SUPPLEMENTAL DISCLOSURE OF CASH-FLOW INFORMATION

Cash paid during year for:

|          |          |          |
|----------|----------|----------|
| Interest | \$ 1,585 | \$ 5,641 |
|----------|----------|----------|

See accompanying notes to consolidated financial statements.

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**BIOMERICA, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**YEARS ENDED MAY 31, 2012 AND 2011**

**1. ORGANIZATION**

Biomerica, Inc. and Subsidiaries (collectively "the Company") are primarily engaged in the development, manufacture and marketing medical diagnostic kits. As of May 31, 2012 and 2011 the Company had one operational unit.

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, 2012 and 2011 include the accounts of Biomerica, Inc. ("Biomerica") as well as the Company's German subsidiary and Mexican subsidiary which have not begun operations. All significant intercompany accounts and transactions have been eliminated in consolidation. During fiscal 2012 and 2011, there were no transactions in ReadyScript, a discontinued operation, and management formally dissolved the corporation during fiscal 2012.

**ACCOUNTING ESTIMATES**

The preparation of 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 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, short-term investments, accounts receivable, commercial bank line of credit, commercial bank equipment loan 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 provides credit in the normal course of business to customers throughout the United States and foreign markets. The Company had one customer which accounted for 37.2% and 22.2% of its sales for the years ended May 31, 2012 and 2011, respectively. The Company performs ongoing credit evaluations of its customers and requires prepayment in some circumstances. At May 31, 2012 and 2011, one customer accounted for 45.6% and 38.5% of gross accounts receivable, respectively.

For the year ended May 31, 2012, two companies accounted for 30.8% of the purchases of raw materials. There were no such concentrations for the year ended May 31, 2011.

## **GEOGRAPHIC CONCENTRATION**

As of May 31, 2012 and 2011, approximately \$538,000 and \$468,000 of Biomerica's gross inventory and approximately \$4,000 and \$7,500, of Biomerica's property and equipment, net of accumulated depreciation and amortization, 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 reserve for bad debt accordingly. Balances over ninety days old are usually reserved for. Any charge-offs are approved by upper level management prior to charging off.

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:

|                   | 2012         | 2011         |
|-------------------|--------------|--------------|
| Raw materials     | \$ 896,000   | \$ 737,000   |
| Work in progress  | 554,000      | 718,000      |
| Finished products | 371,000      | 331,000      |
| Total             | \$ 1,821,000 | \$ 1,786,000 |

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.

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## 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 \$147,297 and \$130,046 for the years ended May 31, 2012 and 2011, respectively.

Management of the Company assesses the recoverability of property and equipment by determining whether the depreciation and amortization of such assets over their remaining lives can be recovered through projected undiscounted cash flows. The amount of impairment, if any, is measured based on fair value (projected discounted cash flows) and is charged to operations in the period in which such impairment is determined by management. Management has determined that there is no impairment of property and equipment at May 31, 2012.

## INTANGIBLE ASSETS

Intangible assets include trademarks, product rights, technology rights and patents, and are accounted for based on 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 \$32,827 and \$17,764 for the years ended May 31, 2012 and 2011, 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. The amount of impairment, if any, is measured based on fair value and charged to operations in the period in which the impairment is determined by management.



## 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.

## STOCK-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.

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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:

|                         |                 |              |
|-------------------------|-----------------|--------------|
|                         | 2012            | 2011         |
| Dividend yield          | 0%              | 0%           |
| Expected volatility     | 77.76-84.97%    | 85.97-86.42% |
| Risk free interest rate | 0.63-0.76%      | 1.87-2.27%   |
| Expected life           | 3.25-3.75 years | 3.75 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, 2012 and 2011, 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 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 \$347,128 and \$420,571 of research and development expenses during the years ended May 31, 2012 and 2011, 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.

The Company accounts for our 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 on 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.

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## **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 \$8,000 and \$9,000 for the years ended May 31, 2012 and 2011, 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 resulting adjustments are presented as a separate component of accumulated other comprehensive income.

## **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 INCOME PER SHARE**

Basic earnings per share is computed as net income divided by the weighted average number of common shares outstanding for the period. Diluted earnings 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 warrants or options not included in the earnings per share calculation for the years ended May 31, 2012 and 2011 was 195,000 and 649,250, respectively.

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

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| For the Years Ended May 31                                  | 2012       | 2011       |
|---|------------|------------|
| Numerator for basic and diluted net income per common share | \$ 548,435 | \$ 157,447 |
| Denominator for basic net income per common share           | 6,887,929  | 6,668,229  |
| Effect of dilutive securities:                              |            |            |
| Options and warrants  | 219,830    | 36,078     |
| Denominator for diluted net income per common share         | 7,107,759  | 6,704,307  |
| Basic net income per common share                           | \$ 0.08    | \$ 0.02    |
| Diluted net income per common share                         | \$ 0.08    | \$ 0.02    |

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## 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 INCOME (LOSS)

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

## RECENT ACCOUNTING PRONOUNCEMENTS

In June 2011, the Financial Accounting Standards Board (“FASB”) issued guidance on the presentation of comprehensive income. This guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The guidance allows two presentation alternatives; present items in net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive, statements of net income and other comprehensive income. This guidance is effective as of the beginning of the fiscal year that begins after December 15, 2011. Early adoption is permitted, but full retrospective application is required under both sets of accounting standards. The Company is currently evaluating which presentation alternative it will utilize.

In September 2011, the FASB issued an amendment to ASC 350, “*Intangibles - Goodwill and Other*”, which simplifies how entities test goodwill for impairment. Previous guidance under ASC 350 required an entity to test goodwill for impairment using a two-step process on at least an annual basis. First, the fair value of a reporting unit was calculated and compared to its carrying amount, including goodwill. Second, if the fair value of a reporting unit was less than its carrying amount, the amount of impairment loss, if any, was required to be measured. Under the amendments in this update, an entity has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads the entity to determine that it is more likely than not that its fair value is less than its carrying amount. If after assessing the totality of events or circumstances, an entity determines that it is not more likely than not that the fair value of the reporting unit is less than its carrying amount, then the two-step impairment test is unnecessary. If the entity concludes otherwise, then it is required to test goodwill for impairment under the two-step process as described under paragraphs 350-20-35-4 and 350-20-35-9 under ASC 350. The amendments are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 and early adoption is permitted. The Company does not believe that the adoption of this standard will have a material

effect on its financial statements.

Other recent Accounting Standards Updates (ASU) issued by the FASB and guidance issued by the SEC did not, or are not believed by management to, have a material effect on the Company's present or future consolidated financial statements.

### 3. INTANGIBLE ASSETS, Net

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

|                               | 2012       | 2011       |
|-------------------------------|------------|------------|
| Patents and licenses          | \$ 245,174 | \$ 195,174 |
| Less accumulated amortization | (50,591)   | (17,764)   |
|                               | \$ 194,583 | \$ 177,410 |

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

|            |    |         |
|------------|----|---------|
| 2013       | \$ | 23,966  |
| 2014       |    | 23,958  |
| 2015       |    | 23,958  |
| 2016       |    | 23,958  |
| 2017       |    | 23,958  |
| Thereafter |    | 74,785  |
| Total      | \$ | 194,583 |

#### 4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

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

|                      | 2012       | 2011       |
|----------------------|------------|------------|
| Accounts payable     | \$ 187,618 | \$ 246,346 |
| Accrued expenses     | 40,036     | 127,156    |
| Deferred rent        | 74,855     | 73,517     |
| Income taxes payable | 59,938     | --         |
| Other                | --         | 4,550      |
|                      | \$ 362,447 | \$ 451,569 |

#### 5. RELATED PARTY TRANSACTIONS

Included in accrued compensation as of May 31, 2012 and 2011 is a vacation accrual of \$84,626 and \$122,039, respectively. Included in the 2012 and 2011 vacation accrual is approximately \$0 and \$40,000, respectively, due to the former chief executive officer's estate. As of May 31, 2011, the Company and the estate had settled on a reduction of the balance due by approximately \$80,000. The remaining balance due, as a result of this settlement, was paid in June 2011.

#### 6. 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 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. 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 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.

Activity as to stock options and warrants outstanding are as follows:

|  | NUMBER OF<br>STOCK OPTIONS<br>AND<br>WARRANTS | WEIGHTED<br>AVERAGE<br>PRICE RANGE<br>PER SHARE | EXERCISE<br>PRICE |
|--|---|---|-------------------|
| Options and warrants outstanding at May 31, 2010 | 1,319,999                                     | \$0.30 - \$1.30                                 | \$0.77            |
| Options granted                                  | 348,000                                       | \$0.38 - \$0.40                                 | \$0.39            |
| Options and warrants exercised                   | (207,500)                                     | \$0.40  | \$0.40            |
| Options and warrants canceled or expired         | (460,249)                                     | \$0.40 - \$0.73                                 | \$0.48            |
| Options and warrants outstanding at May 31, 2011 | 1,000,250                                     | \$0.30 - \$1.30                                 | \$0.57            |
| Options granted                                  | 412,500                                       | \$0.43 - \$0.73                                 | \$0.44            |
| Options and warrants exercised                   | (84,000)                                      | \$0.38 - \$0.73                                 | \$0.59            |
| Options and warrants canceled or expired         | (324,250)                                     | \$0.38 - \$1.30                                 | \$0.71            |
| Options and warrants outstanding at May 31, 2012 | 1,004,500                                     | \$0.30 - \$0.75                                 | \$0.46            |

The weighted average fair value of options and warrants granted during 2012 and 2011, was \$0.44 and \$0.39, respectively. The aggregate intrinsic value of options exercised during 2012 and 2011 was approximately \$8,800 and \$10,200, respectively. The aggregate intrinsic value of options outstanding at May 31, 2012 and 2011, was approximately \$232,000 and \$23,000, respectively. The aggregate intrinsic value of options vested and exercisable at May 31, 2012 and 2011, was approximately \$79,000 and \$3,000, respectively.

At May 31, 2012, total compensation cost related to non-vested stock option awards not yet recognized totaled \$43,569. The weighted-average period over which this amount is expected to be recognized is 3.08 years. The weighted average remaining contractual term of options and warrants that were exercisable at May 31, 2012 was 3.82 years.

The following summarizes information about all of the Company's stock options and warrants outstanding at May 31, 2012. These options are comprised of those granted under the 1999 and 2010 plans.

| RANGE OF<br>EXERCISE<br>PRICES | WEIGHTED<br>NUMBER<br>OUTSTANDING<br>5/31/2012 | AVERAGE<br>REMAINING<br>CONTRACTUAL<br>LIFE IN YEARS | WEIGHTED<br>AVERAGE<br>EXERCISE<br>PRICE | NUMBER<br>EXERCISABLE<br>AT MAY 31, 2012 | WEIGHTED<br>AVERAGE<br>EXERCISE<br>PRICE |
|--------------------------------|--|--|--|--|--|
| \$0.30 - \$0.50                | 809,500  | 3.84   | \$0.42                                   | 214,750                                  | \$0.41                                   |
| \$0.51 - \$0.75                | 195,000  | 3.75   | \$0.66                                   | 185,000                                  | \$0.66                                   |

## STOCK ACTIVITY

In February 2011 the Board of Directors granted stock options for 173,000 options to employees of the Company. The options vests one quarter after one year and then will vest one quarter per year thereafter. The options are at the exercise price of \$0.38 and expire in five years.

In May 2011 the Board of Directors granted stock options for 175,000 options to officers and directors of the Company. The options vested one quarter after one year and then will vest one quarter per year thereafter. The options are at the exercise price of \$0.40 and expire in five years

In January 2012 the Board of Directors granted stock options for 402,500 options to officers, directors and employees of the Company. Options for directors who are not also officers vested one quarter immediately and then will vest one quarter per year thereafter. The options for employees and officers vest one quarter after one year and then will vest one quarter per year thereafter. The options are at the exercise price of \$0.43 and expire in five years.

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In April 2012 the Board of Directors granted stock options for 10,000 shares to an employee. The option vested one quarter immediately and then will vest one quarter per year thereafter. The option is at the exercise price of \$0.73 and expires in five years.

During the fiscal year ended May 31, 2011, options and warrants to purchase 207,500 shares of common stock were exercised at the price of \$0.40 per share. Total proceeds to the Company were \$83,000.

During the fiscal year ended May 31, 2012, options to purchase 84,000 shares of common stock were exercised at the prices ranging from \$0.38 to \$0.73. Total proceeds to the Company were \$47,790.

## 7. INCOME TAXES

Income tax expense from continuing operations for the years ended May 31, 2012 and 2011 consists of the following current provisions:

|           |                 | 2012      | 2011     |
|-----------|-----------------|-----------|----------|
| Current:  |                 |           |          |
|           | U.S. Federal    | \$ --     | \$ --    |
|           | State and local | 63,414    | 1,999    |
|           |                 | 63,414    | 1,999    |
| Deferred: |                 |           |          |
|           | U.S. Federal    | --        | --       |
|           | State and local | 1,600     | --       |
|           |                 | 1,600     | --       |
|           |                 | \$ 65,014 | \$ 1,999 |

Income tax benefit from continuing operations differs from the amounts computed by applying the U.S. Federal income tax rate of 35 percent to pretax loss as a result of the following:

| Years ended May 31,                                  | 2012       | 2011      |
|--|------------|-----------|
| Computed "expected" tax expense (benefit)            | \$ 215,000 | \$ 56,000 |
| Increase (reduction) in income taxes resulting from: |            |           |
| True up of carry forwards and other items            | 30,000     | (53,001)  |
| Change in valuation allowance                        | --         | 11,000    |

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|  |           |          |
|--|-----------|----------|
| State income taxes, net of federal benefit | 36,000    | 9,000    |
| Utilization of NOL carry forward           | (219,000) | --       |
| Research and development tax credits       | (4,000)   | (31,000) |
| Permanent tax differences and other        | 7,014     | 10,000   |
|  | \$ 65,014 | \$ 1,999 |

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The tax effect of significant temporary differences are presented below:

| Years ended May 31,   | 2012       | 2011       |
|---|------------|------------|
| Deferred tax assets:  |            |            |
| Accounts receivable, principally due to allowance for doubtful accounts and sales returns | \$ 46,000  | \$ 13,000  |
| Inventory valuation   | 30,000     | 34,000     |
| Compensated absences and deferred payroll   | 70,000     | 50,000     |
| Net operating loss carryforwards  | 327,000    | 583,000    |
| Tax credit carryforwards  | 83,000     | 99,000     |
| Deferred rent expense   | 31,000     | 30,000     |
| Other   | 77,000     | 70,000     |
| Total deferred tax assets   | 664,000    | 879,000    |
| Less valuation allowance  | (280,000)  | (511,000)  |
|   | 384,000    | 368,000    |
| Deferred tax liabilities:   |            |            |
| Accumulated depreciation of property and equipment  | (146,000)  | (130,000)  |
| Net deferred tax asset  | \$ 238,000 | \$ 238,000 |
| Deferred tax assets, current portion  | \$ 177,000 | \$ 127,000 |
| Deferred tax assets, long-term portion  | 61,000     | 111,000    |
|   | \$ 238,000 | \$ 238,000 |

The Company has provided a valuation allowance of \$280,000 and \$511,000 as of May 31, 2012 and 2011, respectively. Because the Company has not achieved taxable net income consistently over the previous four fiscal years, predicting future taxable income is difficult and influenced by many factors. After analyzing the Company's tax position, management has provided an allowance for the uncertainty of its future income. The net change in the valuation allowance for the years ended May 31, 2012 and 2011 was a decrease of \$231,000 and an increase of \$11,000, respectively.

At May 31, 2012 and 2011, the Company has federal income tax net operating loss carryforwards of approximately \$848,000 and \$1,595,000 respectively. Of the reported net operating loss carryforwards, approximately \$211,000 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 \$74,000 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 2021. At May 31, 2012 and 2011, the Company has California state income tax net operating loss carryforwards of approximately \$527,000 and \$439,000, respectively. The state net operating loss carryforwards begin to expire in 2025.

At May 31, 2012 and 2011, the Company has federal research and development tax credit carryforward of approximately \$83,000 and \$76,000, respectively. The federal credits begin to expire in 2027. The Company also had similar credit carry forwards for state purposes of \$16,000 and \$0, respectively, as \$21,000 were utilized in 2012.

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, 2012 and 2011, 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 financial statements. The Company is no longer subject to any significant U.S. federal tax examinations by tax authorities for years before fiscal year 2008.

**8. BUSINESS SEGMENTS**

Geographic information regarding net sales is approximately as follows:

|                 | 2012         | 2011         |
|-----------------|--------------|--------------|
| Net sales:      |              |              |
| Europe          | \$ 2,533,000 | \$ 2,483,000 |
| United States   | 1,074,000    | 1,160,000    |
| Asia            | 2,420,000    | 1,153,000    |
| South America   | 2,000        | 28,000       |
| Middle East     | 22,000       | 45,000       |
| Other foreign   | 30,000       | 30,000       |
| Total net sales | \$ 6,081,000 | \$ 4,899,000 |

**9. 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. The initial base rent was set at \$18,490 per month increasing to \$22,080 through August 31, 2016, with a security deposit of \$22,080. The following is a schedule of rent payments due under the terms of the lease:

|                      |              |
|----------------------|--------------|
| Years Ending May 31, |              |
| 2013                 | \$ 240,684   |
| 2014                 | 247,902      |
| 2015                 | 255,363      |
| 2016                 | 263,031      |
| 2017                 | 66,240       |
| Total                | \$ 1,073,220 |

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 2012 was \$235,984 and for fiscal 2011 was \$231,903. Net rent expense for fiscal 2012 and 2011 was \$202,984 and \$228,903, respectively. The Company received \$33,000 and \$3,000 in fiscal 2012 and 2011, respectively, in income from a temporary sublease, which offset total rent expense. Rent expense for the Mexico facility for fiscal 2012 and 2011 was \$36,302 and \$35,584, 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.

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## 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, 2012.

## CONTRACTS

On March 27, 2009, the Company signed an Asset Purchase Agreement with a European company for the purchase of certain technology related to the manufacture of certain medical diagnostic tests. Consideration for this purchase was a nominal deposit upon signing the agreement and a nominal transfer fee upon successful commencement of production of the products. A royalty shall be paid for five years beginning on the date of first sale of finished product derived from the purchased assets. Royalty payments of 10% of sales are due on these products for a period of five years. Royalty expense for this license was approximately \$5,500 and \$6,000 for the years ended May 31, 2012 and 2011, respectively.

In October 2009, the Company entered into a non-exclusive, worldwide, perpetual, irrevocable, and transferable cross-license agreement to acquire technology and intellectual property from and make available its technology and intellectual property related to enzyme-linked immunosorbent assay products to be marketed by the Company. Pursuant to the terms of the license agreement, the Company has paid \$25,000 for the license for six products, with a similar amount to be paid for each of two additional products as they are transferred. The Company will be amortizing the costs for these licenses over a ten year period. As part of this agreement, the Company must pay royalties on future sales of these products between 4% and 8% and is eligible to receive royalties from certain of its products licensed in the same percentages. The Company accrues this royalty when it becomes payable. The Company had incurred approximately \$16,500 and \$3,750 in royalty expense during fiscal 2012 and 2011, respectively.

In May 2010, the Company acquired from an inventor the exclusive, perpetual license to a United States patent applicable to the measurement of thiopurine methyltransferase within patients prior to commencing treatment with thiopurine drugs. The product is currently being redeveloped by the Company. Pursuant to the terms of the license agreement, the Company was granted an exclusive, worldwide, perpetual license to manufacture, market, distribute and sell the products contemplated by the patents subject to the payment of \$25,000 as reimbursement to the patent holder for legal and other costs associated with obtaining the patent, which was paid in June 2010. The Company is amortizing the initial cost of \$25,000 for this license over a ten year period. As of May 31, 2012 the Company had amortized \$5,000 of the license. As part of this agreement, the Company must pay royalties on future sales of these products between 4% and 8% through September 30, 2022. The agreement also has minimum escalating royalty

payments which must be made for the Company to keep its exclusivity for the license. The Company accrues this royalty when it becomes payable. Royalty in the amounts of \$10,294 and \$0, respectively, was recorded for the years ended May 31, 2012 or 2011.

On October 19, 2010, the Company signed an agreement with a university to acquire the rights to manufacture and market certain products using two patents owned by the university. The Company paid a license issue fee of \$15,000 initially and will pay royalties on net sales quarterly. The Company has amortized approximately \$12,300 of this licensing fee as of May 31, 2012. Royalty expense for this license was approximately \$8,000 and \$4,000 for the years ended May 31, 2012 and 2011, respectively.

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 \$30,000 and \$57,000 is included in cost of sales for these agreements for the years ended May 31, 2012 and 2011, respectively. 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 3.4% and 7.2% of total sales for the years ended May 31, 2012 and 2011, respectively. The Company may license other products or technology in the future as it deems necessary for conducting business.

## 10. DEBT

On February 13, 2009, the Company entered into a Small Business Banking Agreement with Union Bank for a one year business line of credit (the "Line") in the amount of \$400,000. The interest rate for the line of credit was the prime rate in effect on the first day of the billing period, as published in the Wall Street Journal Prime West Coast Edition, plus a spread of 1.00%. Minimum monthly payments are the sum of (i) the amount of interest charge for the billing period, plus (ii) any amount past due, plus (iii) any fees, late charges and/or out-of-pocket expenses assessed. If the Line is not renewed as of the last day of the term of the Line, the entire unpaid balance of the Line, including unpaid fees and charges will be due and payable. The Company has granted the bank security interest in the assets of the Company as collateral. The Company has renewed this line each year. The Line expires February 24, 2013. The Company owed \$43,000 on this Line as of May 31, 2012.

On February 13, 2009, the Company entered into a Small Business Bank Agreement with Union Bank for an equipment loan ("Loan") for \$133,000 and an interest rate of 6.50%. Loan proceeds were disbursed in one single funding on March 5, 2009. Certain related equipment serves as collateral for the loan. The Company had a loan balance of \$35,390 as of May 31, 2011. The loan was paid in full during fiscal 2012.

## 11. OTHER INCOME

On October 29, 2010, the Company was notified that it had been awarded a total cash grant of approximately \$357,000 under the Qualifying Therapeutic Discovery Project program administered under section 48D of the Internal Revenue Code. The grant (net of expenses related to consulting services for the grant application process of approximately \$71,000) was included in other income for the year ended May 31, 2011 was \$285,969. The Company did not receive any grants in fiscal 2012.

During the year ended May 31, 2012, the Company experienced water damage from a burst pipe. Expenses of \$33,522 were incurred as a result of this. Property and equipment amounting to \$68,106 were purchased to replace damaged, fully depreciated equipment and fixtures. The Company's insurance company reimbursed the Company \$101,628, which covered approximately all of its expenses plus cost of replacement property and equipment, resulting in a gain of approximately \$102,000.