BIOMERICA INC
Form 10-K
August 30, 2011

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-K**

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

**For The Fiscal Year Ended May 31, 2011**

or

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

For The Transition Period From _____ To _____

**Commission File Number: 0-8765**

**BIOMERICA, INC.**

(Exact Name of registrant as specified in its charter)

**Delaware**

**95-2645573**

(State or other jurisdiction of

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

Incorporation of organization)

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

**92614**

(Address of principal executive offices)

(Zip Code)

REGISTRANT'S TELEPHONE NUMBER:

**(949) 645-2111**

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

**None**

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

(Title of each class)

(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 Date 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. [X]

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

Large Accelerated Filer [ ]

Accelerated Filer [ ]

Non-Accelerated Filer [ ]

Smaller Reporting Company [X]

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

Yes [ ]

No [X]

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 5,332,647 shares held by non-affiliates and the closing price of $0.39 per share for Common Stock in the over-the-counter market as of November 30, 2010): $2,079,732.

Indicate the number of shares outstanding of each of the registrant's common stock, par value $0.08, outstanding as of August 29, 2011: 6,868,339

DOCUMENTS INCORPORATED BY REFERENCE: Part III contains information incorporated by reference to the Company's proxy statement for its 2011 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, 2011. 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.

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.

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 FDA for diagnostic use, but can be sold in various foreign countries.

Biomerica maintains its headquarters in Irvine, California where it houses administration, research and 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) and also incurred significant costs of severance in the discontinuation of the research group.

Biomerica has undergone no material change in the mode of conducting its business other than as described above. The Company did move its facilities in fiscal 2010 and in doing so disposed of approximately $282,000 of fixed assets and leasehold improvements (these assets were almost fully depreciated-the Company realized a loss for the portion that was not depreciated of $6,107) and incurred other moving expenses. The Company is increasing its efforts to license technology from other companies in order to increase its product line and bring new products to market at a faster pace.

**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 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 is engaged in research and development to broaden its diagnostic product line in specific areas. 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, 2011 and 2010 aggregated $420,571 and $455,171, respectively.

Biomerica eliminated its internal research group (two scientists) in July 2010 in favor of licensing in new technology from outside institutions in order to more rapidly expand its product offerings and time to market, however the Company continued to incur research and development costs (which are classified under Research and Development ) utilizing manufacturing personnel in an effort to complete the development of its newly licensed products.

**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, 2011 and 2010 the Company had one customer which accounted for 22.2% and 23.5%, respectively, of consolidated sales.

**BACKLOG**

At May 31, 2011 and 2010 Biomerica had a backlog of approximately $256,000 and $8,000, 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, 2011 and 2010, no vendor 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 inventory 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 0157 Elisa Kit (Class I Exempt), Verotoxin Elisa Kit (Class I Exempt) and C. Difficile Antibody Elisa Kit.

Class II - GAP IgG H. Pylori ELISA kit, GAP IgM H. Pylori ELISA kit, Anti-thyroglobulin ELISA kit, anti-TPO 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, C-Peptide ELISA kit, Myoglobin ELISA, Troponin I ELISA, HS-CRP ELISA, Allerquant Food Intolerance Kits, Allerquant Food Additive Intolerance Kit, Gliadin IgG and IgA kits, Transglutaminase IgA kit, 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, drugs of abuse rapid tests, EZ-HP Professional, EZ-HP OTC, Fortel Cat Allergy Test, Fortel Dog Allergy Test, Fortel Dust Mite Allergy Test, Intrinsic Factor Autoantibodies Elisa Kit, LKM-1 Autoantibodies IgG Elisa Kit, Cryptosporidium Elisa Kit, Giardia Elisa Kit, E. Histolytica Elisa Kit, Anti-Glidin IgG Elisa Kit, Anti-Gliadin IgA Elisa Kit and Transglutaminase Elisa Kit.

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

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 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 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

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 Kit

LKM-1 Autoantibodies IgG Kit

Camplylobacter Elisa Kit

Cryptosporidium Elisa Kit

E. Coli 0157 Elisa Kit

Giardia Elisa Kit

Verotoxin Elisa Kit

C. Difficile Antibody Elisa Kit

E. Histolytica Elisa Kit

Anti-Gliadin IgG Elisa Kit

Anti-Gliadin IgA Elisa Kit

Transglutaminase 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 subsidiary 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 |
|---|---|
| | 2011 |

2010

Europe

$

2,483,000

/50.7 %

$

2,565,000

/50.5 %

United States

1,160,000

/23.7 %

1,051,000

/20.8 %

Asia

1,153,000

/23.5 %

1,367,000

/26.9 %

S. America

28,000

/0.6 %

45,000

/0.8 %

Middle East

45,000

/0.9 %

34,000

/0.7 %

| | | |
|---|---|---|
| Other foreign | | |
| | 30,000 | |
| | /0.6 | % |
| | 13,000 | |
| | /0.3 | % |
| Total Revenues | | |
| | $ | |
| | 4,899,000 | |
| | /100 | % |
| | $ | |
| | 5,075,000 | |
| | /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**

We registered the tradenames "Fortel", "Isletest", "Nimbus" and "GAP" with the Office of Patents and Trademarks on December 31, 1985. Our unregistered tradenames are "EZ-Detect", "Candiquant," "Candigen", "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

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 four 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 expensed approximately $3,750 and $0 during fiscal 2011 and 2010, 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. At May 31, 2011 the Company has amortized $2,500 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. No royalty was accrued or expensed for the years ended at May 31, 2011 and 2010.

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 $4,254 of this licensing fee as of May 31, 2011. Royalty expense for this license was approximately $4,000 for the year ended May 31, 2011.

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 $57,000 and $121,000 is included in cost of sales for these agreements for the years ended May 31, 2011 and 2010, respectively. In fiscal 2011, the Company is 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 7.2% and 15.6% of total sales for the years ended May 31, 2011 and 2010, 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, 2011 and 2010, the Company employed 28 and 33 employees, respectively, of whom 1 and 2, respectively, were part-time employees in the United States. The following is a breakdown between departments:

| | 2011 | 2010 |
|---|---|---|
| Administrative | 4 | 4 |
| Marketing & Sales | 3 | |

| | | |
|---|---|---|
| | 3 | |
| Research & Development | | |
| | 0 | |
| | 2 | |
| Production and Operations | | |
| | 21 | |
| | 24 | |
| Total | | |
| | 28 | |
| | 33 | |



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In addition, Biomerica contracts with Lancer for the services of 13 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 over 22% of our total sales) 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.



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**ITEM 1B. UNRESOLVED STAFF COMMENTS**

**None.**

**ITEM 2. PROPERTIES**

On June 18, 2009, the Company entered into an agreement to lease a building from an unaffiliated party in Irvine, California, commencing September 1, 2009 and ending August 31, 2016. The initial base rent was set at $18,490 with a security deposit of $22,080. In October and November 2009 the Company moved its operations to this facility. Total rent expense in the U.S. for fiscal 2010 was $236,872 and for fiscal 2011 was $231,903. Rent expense for the Mexico facility for fiscal 2011 and 2010 was $35,584 and $31,134, respectively.

During fiscal 2009 and from June through November of fiscal 2010 the Company leased its facilities on a month-to-month basis while it negotiated, planned and executed its move. Those facilities were owned and operated by Ms. Janet Moore (an officer and director of the Company), Ilse Sultanian, Susan Irani Rigdon and Jennifer Irani, some of whom are shareholders. The rent was $14,000 per month. Management believed that there would have been no significant difference in the terms of the property rental if the Company was renting from a third party.

**ITEM 3. LEGAL PROCEEDINGS**

None.

**ITEM 4. REMOVED AND RESERVED.**

**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.

Bid Prices

| | High | Low |
|---|---|---|
| Quarter ended: | | |
| May 31, 2011 | $ 0.48 | $ 0.41 |
| February 28, 2011 | $ 0.49 | $ |

0.34

November 30, 2010

$

0.45

$

0.39

August 31, 2010

$

0.47

$

0.38

May 31, 2010

$

0.53

$

0.40

February 29, 2010

$

0.44

$

0.36

November 30, 2009

$

0.45

$

0.35

| August 31, 2009 | |
|---|---|
| | $ |
| 0.69 | |
| | $ |
| 0.42 | |

As of May 31, 2011, the number of holders of record of Biomerica's common stock was approximately 863, 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.



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We did not issue any equity securities that were not registered under the Securities Act during our fiscal year ended May 31, 2011.

We did not purchase any of our shares of common stock or other securities during our fiscal year ended May 31, 2011.

The table below provides information relating to our equity compensation plans as of May 31, 2011:

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

| | | |
|---|---|---|
| Plans approved by | | |
| | 1,000,250 | |
| | $0.57 | |
| | 519,000 | |
| Securities holders | | |

**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 or urine 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.

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. Frequently, results were not available until at least the following day. We believe that rapid point of care tests may be as accurate as laboratory tests when used properly and they require no instrumentation, give reliable results in minutes and can be performed with confidence in the home or the physician's office.



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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 FDA for diagnostic use, but can be sold in various foreign countries.

A part of Biomerica's manufacturing and assembly operations is located in Mexicali, Mexico, as part of the maquiladora program in order to reduce the cost of manufacturing and compete more effectively worldwide. Biomerica maintains its headquarters in Irvine, California where it houses administration, research and development,

sales and marketing, customer services and some manufacturing operations. Biomerica has also established subsidiaries in Mexicali and Germany for future use. After the year-end the Company eliminated its dedicated research department in order to follow its current strategy of licensing technology from other institutions.

**RESULTS OF OPERATIONS**

Fiscal 2011 Compared to Fiscal 2010

During fiscal 2010 the Company moved its facilities from Newport Beach to Irvine, California. This move impacted expenses in every department in that fiscal year. The Company incurred direct moving costs of approximately $225,000. The Company incurred some overlapping rent and related expenses during the transition and continued to rent a small amount of space at the prior facility for several months after the main move. The move affected the production output for a couple of months during the move and set-up period and contributed to a larger than normal production scrap. Scrap problems as a result of the move have since been resolved.

Our consolidated net sales were $4,899,375 for fiscal 2011 compared to $5,075,222 for fiscal 2010. This represents a decrease of $175,847, or 3.5% for fiscal 2011. The Company realized an increase in sales in the U.S. of approximately $109,000 primarily to a major chain drug store but this was offset by decreases in Asia. Sales in Asia were less due to sales incentives and new product registration costs (provided in the form of free product which would have ordinarily sustained demand for our product). There was also a backlog of approximately $256,000 (as of May 31, 2011) which would have increased sales if the products had been shipped and reduced the cost of goods as a percentage of sales in the period.

Cost of sales in fiscal 2011 as compared to fiscal 2010 decreased from $3,514,455 to $3,373,786, or by $140,669. The percentage of cost of sales relative to sales decreased from 69.2% to 68.9%, or by 4.2%, due to various factors. At May 31, 2011, the Company had accrued in other liabilities approximately $59,100 of expenses related to free product (scheduled to be shipped in the first quarter of fiscal 2012) due a large distributor for sales incentives. This contributed to a 1.2% increase in cost of goods as a percentage of sales.

Selling, general and administrative costs decreased in fiscal 2011 as compared to fiscal 2010 from $1,470,116, to $1,237,279, or by $232,837 (15.8%). The decrease was primarily a result of the moving expenses incurred in fiscal 2010 of approximately $225,000 as well as a reduction in accrued vacation expense of approximately $80,000 in fiscal 2011 which had been due to the former chief executive officer s estate and which was settled upon with the estate at a lower amount. These reductions in fiscal 2011 were offset by increases in wages and wage related expenses and trade show expenses.

Research and development expense was $420,571 in fiscal 2011 as compared to $455,171 in fiscal 2010. This is a decrease of $34,600 (7.6%). While the Company did eliminate its internal research group (two scientists) in July 2010, it did still expend considerable funds in the effort to ready certain new products for market (both internally developed and licensed from others) and also incurred significant costs of severance in the discontinuation of the research group.

Interest expense decreased from $12,323 to $5,830 in fiscal 2011 as compared to fiscal 2010, or $6,493 (52.7%). The change in interest expense resulted from decreased balances pertaining to accrued wages payable and the equipment loan. Interest income decreased from $14,713 to $7,367 due to lower interest rates and lower cash balances.

Other income increased from $17,675 to $290,170, an increase of $272,495. Most of the increase in other income in fiscal 2011 as compared to 2010 was derived from a grant received under the Qualifying Therapeutic Discovery Project, as discussed under Liquidity and Capital Resources below.



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LIQUIDITY AND CAPITAL RESOURCES

As of May 31, 2011, the Company had cash and cash equivalents in the amount of $989,270, as compared to $1,055,206 of cash and cash equivalents as of May 31, 2010. As of May 31, 2011 and 2010, the Company had working capital of $3,261,418 and $3,176,438 respectively. During 2011, cash provided by operations was $328,803 as compared to cash used in fiscal 2010 of $236,980. The increase in fiscal 2011 was primarily due to $285,969 recorded to net income for the grant received during fiscal year ended May 31, 2011. It also was the result of our collection on accounts receivable balances offset by the pay down of accrued compensation and changes in accounts payable and accrued expenses and other non-cash adjustments. During fiscal 2011, cash used in investing activities was $431,683 as compared to $269,402 in fiscal 2010. Cash of $141,084 and $315,521 for fiscal 2011 and 2010, respectively, was used for the purchase of property and equipment. In addition, in fiscal 2011 the Company invested $165,324 in a distributor of its products and $125,275 to license new products as compared to $0 and $53,881, respectively in fiscal 2010. Cash provided by financing activities in fiscal 2011 was $37,891 as compared to cash used in financing activities of $32,448 in fiscal 2010. The increase was primarily due to the exercise of stock options.

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, of which approximately $217,000 (net of expenses related to consulting services for the grant application process of $43,428) relates to qualifying expenses the Company previously incurred and was received

during the second quarter of fiscal 2011. The award and related expense of the remainder of the grant of approximately $140,000 (less grant application services of approximately $28,000) were accrued for as of May 31, 2011. These funds were received during June 2011. Total net income from these grants which was included in other income for the year ended May 31, 2011, was $285,969.

On February 13, 2010, 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 must maintain for not less than thirty consecutive days in every calendar year, a period in which all amounts due under the revolving credit agreements with the bank are at a zero balance. This Line expired February 13, 2011 and was renewed on June 7, 2011 and expires February 24, 2012. The Company did not owe anything on this Line as of May 31, 2011.

**OFF BALANCE SHEETS ITEMS**

There were no off-balance sheet arrangements as of May 31, 2011.

**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 the Allowance for Doubtful Accounts, Inventory Reserves for Obsolescence and Declines in Market Value, Impairment of Long-Lived Assets, Stock Based Compensation, and Income Tax Accruals.

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.



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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.

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, 2011, that $511,000 of its deferred tax asset should be reserved for. Management has determined that the tax asset of $238,000 as of May 31, 2011 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 affect 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; 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, 2011, 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, 2011, 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 2011 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, 2011.

**ITEM 11. EXECUTIVE COMPENSATION**

This information is incorporated by reference to the Company's proxy statement for its 2011 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, 2011.

**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 2011 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, 2011.

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

In fiscal 2003, Biomerica entered into an agreement with Lancer whereby Biomerica agreed to pay an initial shelter fee of $5,000 with additional monthly payments of $2,875 for use of the Lancer de Mexico facilities to produce and manufacture Biomerica products. The monthly payments are due as long as Biomerica produces its products at the Lancer de Mexico facility. At May 31, 2011, Biomerica has paid all applicable shelter fees and rent due. From June through November of fiscal 2010, the Company leased its facilities, on a month-to-month basis, from an officer and director of the Company as well as certain shareholders. The rent was approximately $14,000 per month.

Other information regarding related transactions is incorporated by reference to the Company's proxy statement for its 2011 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, 2011.

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

Please refer to the Company s proxy statement for its 2011 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, 2011.

**POLICY ON AUDIT COMMITTEE PRE-APPROVAL OF AUDIT AND NON-AUDIT SERVICES**

The Audit Committee has the responsibility of appointing the independent audit firm and overseeing their work. The Audit Committee pre-approves all audit and related services. Should the audit committee pre-approve any services other than audit and related services, it evaluates whether the services would compromise the auditor's independence.

Of the services provided in fiscal 2011 and 2010, all fees and services were pre-approved by the audit committee.

**PART IV**

**ITEM 15. EXHIBITS LIST AND REPORTS ON FORM 8-K**

| Exhibit No. | Description |
| --- | --- |
| 3.1 | Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on September 22, 1971 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to |

Registration Statement on Form S-1, Commission File No. 2-83308).

3.2

Certificate of Amendment to Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on February 6, 1978 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).

3.3

Certificate of Amendment to Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on February 4, 1983 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).

3.4

Certificate of Amendment to Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on January 19, 1987 (incorporated by reference to Exhibit 3.4 filed with Form 8 Amendment No. 1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended May 31, 1987).

3.5

Certificate of Amendment of Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on November 4, 1987 (incorporated by reference to Exhibit 3.1 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).

3.6

Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 filed with Amendment No. 1 to Registration Statement on Form S-1, Commission File No. 2-83308).

3.7

Certificate of Amendment of Certificate of Incorporation of Registrant filed with the Secretary of the State of Delaware on December 20, 1994 (incorporated by reference to Exhibit 3.7 filed with Registrant's Annual Report on Form 10-KSB for the fiscal year ended May 31, 1995).

3.8

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,