

Edgar Filing: BIOMERICA INC - Form 10KSB

BIOMERICA INC  
Form 10KSB  
September 10, 2004

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

-----  
FORM 10-KSB

[X] ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE  
ACT OF 1934

FOR THE FISCAL YEAR ENDED MAY 31, 2004

COMMISSION FILE NUMBER: 0-8765  
-----

BIOMERICA, INC.  
-----

(Small Business Issuer in its Charter)

DELAWARE  
-----

(State or other jurisdiction of  
incorporation or organization)

95-2645573  
-----

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

1533 MONROVIA AVENUE, NEWPORT BEACH, CA  
-----

92663  
-----

(Address of principal executive offices)

(Zip Code)

Issuer's Telephone Number:

(949) 645-2111

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

(Title of each class)  
-----

(Name of each exchange on which registered)  
-----

NONE

OTC-Bulletin Board

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

(Title of each class)  
-----

COMMON STOCK, PAR VALUE \$0.08

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 [ ]

Check if disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained herein, and will not be contained, to the best of issuer's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.  
[X]

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes [ ] No [X]

State issuer's revenues for its most recent fiscal year: \$9,168,833.

## Edgar Filing: BIOMERICA INC - Form 10KSB

State the aggregate market value of the voting and non-voting stock held by non-affiliates of the issuer (based upon 4,400,504 shares held by non-affiliates and the closing price of \$0.45 per share for Common Stock in the over-the-counter market as of July 31, 2004): \$1,980,227.

Number of shares of the issuer's common stock, par value \$0.08, outstanding as of August 27, 2004: 5,752,431.

DOCUMENTS INCORPORATED BY REFERENCE: none

Transitional Small Business Disclosure Format                      YES [ ]    NO [X]

### PART I\*

#### ITEM 1. DESCRIPTION OF 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. We changed our corporate name in February 1983 to NMS Pharmaceuticals, Inc., and in November 1987 to Biomerica, Inc. During fiscal 2004 we had one operational subsidiary, Lancer Orthodontics, Inc. ("Lancer"), an international manufacturer of orthodontics products.

Lancer is engaged in the design, manufacture and distribution of orthodontic products. Biomerica's direct ownership percentage of Lancer is 25.0% and its direct and indirect (via agreements with certain shareholders) voting control over Lancer is greater than 50% as of May 31, 2004.

The Company adopted a formal plan in April 2001 to discontinue operations of its ReadyScript subsidiary. Certain assets were written off during the closure and subsequent to then which were recorded as losses in the consolidated financial statements. The subsidiary is being reported in the financial statements as a discontinued operation because it is no longer an operating entity.

##### OUR MEDICAL DEVICE BUSINESS

Our existing medical device business is conducted through two companies: (1) Biomerica, Inc., engaged in the human diagnostic products market and (2) Lancer Orthodontics, Inc., engaged in the orthodontic products market.

##### BIOMERICA - DIAGNOSTIC PRODUCTS

Biomerica 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 three markets: 1) clinical laboratories, 2) physicians offices and 3) 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.

## Edgar Filing: BIOMERICA INC - Form 10KSB

Technological advances in medical diagnostics have made it possible to perform diagnostic tests within the home and the physician's office, rather than in the clinical laboratory. One of our main 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 prompt diagnosis and early detection. Until recently, 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 are 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. The majority of our over-the-counter rapid tests are FDA cleared.

Our clinical laboratory diagnostic products include tests for thyroid conditions, food allergies, H. pylori, diabetes and others. These diagnostic test kits utilize enzyme immunoassay or radioimmunoassay 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.

2

During fiscal 2002 we introduced the Aware Breast Self-Examination Pad, which is a patented, FDA-cleared polyurethane pad containing a silicone lubricant. The pad is designed to enhance the sense of touch by reducing friction between the fingers and the skin. The pad is packaged with an instructional video which teaches the proper techniques for performing breast self-examination.

During fiscal 2003 we entered into an agreement with Sanguis Bio Tech, Inc., whereby we acquired intellectual assets along with ancillary tangible assets such as fixed assets and inventory. The intellectual assets consisted of five clinical laboratory products. Two Sanguis employees became employees of Biomerica.

### LANCER ORTHODONTICS, INC. -- ORTHODONTIC PRODUCTS

Lancer is engaged in developing, manufacturing, and selling orthodontic products. Its products are sold worldwide through a direct sales force and distributors. Lancer conducts its operations at two facilities, one of which is located at 253 Pawnee Street, San Marcos, California 92069-2347 and the other in Mexicali, Mexico.

Lancer's product line includes preformed bands, direct bonding brackets, buccal tubes, arch wires, lingual attachments and related accessories were used by orthodontics and dentists in treating their patients. The foregoing are assembled to standard prescriptions or the specifications of private label customers. Lancer also markets products which are purchased and resold to orthodontists, including sealants, adhesives, elastomerics, headgear cases, retainer cases and preformed arches.

Most of Lancer's manufacturing and shipping operations are located in Mexicali, Mexico, in order to reduce the cost of manufacturing and compete more effectively worldwide. Lancer maintains its headquarters in San Marcos, California where it houses administration, engineering, sales and marketing, and customer services.

Lancer has undergone no material change in the mode of conducting its

## Edgar Filing: BIOMERICA INC - Form 10KSB

business other than as described above and it did not dispose of any material amount of its assets during the fiscal year ended May 31, 2004.

### DISCONTINUED OPERATIONS

Biomerica's ReadyScript subsidiary was a development-stage enterprise and required the raising of a significant amount of capital to fund its short-term working capital needs. The ReadyScript operations were discontinued in May 2001. The net liabilities and operating results of ReadyScript are shown separately in the accompanying consolidated financial statements as discontinued operations.

### LIQUIDITY AND GOING CONCERN

These consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has operating and liquidity concerns due to historically reporting net losses and negative cash flows from operations. Biomerica's shareholder's line of credit (Notes 1 and 6) expired on September 13, 2003. The unpaid principal and interest were converted into a note payable bearing interest at 8% and due September 1, 2004. No payments are currently due on the note through September 1, 2004.

The Company has suffered substantial recurring losses from operations over the last several years. Biomerica has funded its operations through debt and equity financings, and may have to do so in the future. ReadyScript operations were discontinued in May 2001 and Allergy Immuno Technologies, Inc. was sold in May 2002. ReadyScript and Allergy Immuno Technologies, Inc. were major contributors to the Company's losses. In fiscal years 2004 and 2003, the Company reduced operating costs through certain cost reduction efforts and plans to concentrate on its core business in Lancer and Biomerica to increase sales.

3

Management believes that cash flows from operations coupled with reduced costs and anticipated increased sales should enable the Company to fund operations for at least the next twelve months. Should the Company be unable to reduce costs adequately, increase sales or be unable to secure additional financing, the result for the Company could be the inability to continue as a going concern.

The Company will continue to have limited cash resources. Biomerica, as a parent entity, has no open or existing, operating line of credit or loans on which it can draw any debt financing and we are not currently in negotiations to obtain such financing. Although the Company's management recognizes the imminent need to secure additional financing or increase sales, there can be no assurance that the Company will be successful in doing so or, if the Company does consummate a financing, that the terms and conditions of such financing will not be unfavorable to shareholders.

Our independent certified public accountants have concluded that these factors, among others, raise substantial doubt as to the Company's ability to continue as a going concern for a reasonable period of time, and have, therefore modified their report in the form of an explanatory paragraph describing the events that have given rise to this uncertainty. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

### PRODUCTION

Most of our diagnostic test kits are processed and assembled at our

## Edgar Filing: BIOMERICA INC - Form 10KSB

facilities in Newport Beach, California and in Mexicali, Mexico. During fiscal 2003 we established a manufacturing facility in Mexicali, Mexico, in a building that we share with Lancer Orthodontics. We have moved some of our diagnostic manufacturing to that facility. We subcontract with Lancer to provide labor and other services. Production of diagnostic tests can involve formulating component antibodies and antigens in specified concentrations, attaching a tracer to the antigen, filling components into vials, packaging and labeling. We continually engage in quality control procedures to assure the consistency and quality of our products and to comply with applicable FDA regulations.

All manufacturing production is regulated by the FDA Good Manufacturing Practices for medical devices. We have an internal quality control unit that monitors and evaluates product quality and output. In addition, we employ a qualified external quality assurance consultant who monitors procedures and provides guidance in conforming with the Good Manufacturing Practices regulations. We either produce our own antibodies and antigens or purchase these materials from qualified vendors. We have alternate, approved sources for raw materials procurement and we do not believe that material availability in the foreseeable future will be a problem.

During fiscal 2002, the Lancer facility in Mexico was incorporated as Lancer Orthodontics de Mexico ("Lancer de Mexico"), a wholly-owned subsidiary of Lancer. This subsidiary now administers services previously provided by an independent manufacturing contractor. A lease was negotiated in the name of Lancer de Mexico, effective April 1, 2001, for the 16,000 square foot facility already in use for Lancer's Mexican operations. Mexican utility and vendor obligations were also converted to the Lancer de Mexico name. This conversion eliminated the expense of an administrative fee and is expected to provide better control in meeting future obligations. The conversion had no material effect on manufacturing operations.

Should Lancer discontinue operations in Mexico, it is responsible for accumulated employee seniority obligations as prescribed by Mexican law. At May 31, 2004, this obligation was approximately \$397,000. Such obligation is contingent in nature and accordingly has not been accrued in either company's financial statements.

### 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. Lancer is engaged in development programs to improve and expand its orthodontic products and production techniques. Lancer consults frequently with practicing orthodontists.

4

Consolidated research and development expenses incurred by Biomerica for the years ended May 31, 2004 and 2003 aggregated approximately \$274,000 and \$263,000, respectively. Lancer is also engaged in, and intends to continue development programs directed toward improving its orthodontics products and production techniques. Of the above expenses approximately \$116,000 and \$107,000 for fiscal 2004 and 2003, respectively, are for Lancer's product development.

### MARKETS AND METHODS OF DISTRIBUTION

Biomerica has approximately 400 current customers for its diagnostic business, of which approximately 100 are distributors and the balance are hospital and clinical laboratories, medical research institutions, medical

## Edgar Filing: BIOMERICA INC - Form 10KSB

schools, pharmaceutical companies, chain drugstores, wholesalers and physicians' offices.

We rely on unaffiliated distributors, advertising in medical and trade journals, exhibitions at trade conventions, direct mailings and an internal sales staff to market our diagnostic products. We target three main markets: (a) clinical laboratories, (b) physicians' offices, and (c) over-the-counter drug stores. Separate marketing plans are utilized in targeting each of the three markets.

Lancer sells its products directly to orthodontists through company-paid sales representatives in the United States. At the end of its fiscal year, Lancer had five (three telesales) sales representatives in the United States and Mexico, all of whom are employees of Lancer. We believe that all Lancer products sold in the U.S. comply with FDA regulations.

In selected foreign countries, Lancer sells its products directly to orthodontists through its international marketing division. Lancer also sells its products through distributors in certain foreign countries and to other companies on a private label basis. Lancer has entered into a number of distributor agreements whereby it granted the marketing rights to its products in certain sales territories in Central America, South America, Europe, Canada, Australia, and Japan. The distributors complement the international marketing department which was established in 1982 and currently employs three people in the United States and one in Mexico.

On a consolidated basis no customer accounted for 10% or more of the consolidated sales in the fiscal years ended May 31, 2004 and 2003. No customer accounted for 10% or more of Lancer Orthodontics' sales for the fiscal year ended May 31, 2004 and 2003. On an unconsolidated basis Biomerica has one customer which accounts for greater than 10% of its sales for the years ended May 31, 2004 and 2003.

### BACKLOG

At May 31, 2004 and 2003 Biomerica had a backlog of approximately \$92,000 and \$110,000 respectively. As of May 31, 2004 and 2003, Lancer had a backlog of approximately \$124,000 and \$35,000, respectively. The change in Lancer's backlog is primarily attributable to problems related to software upgrades to their computer system. Neither Biomerica nor Lancer's businesses are subject to significant seasonal fluctuations.

### 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. No company accounted for more than 10% of purchases for the years ended May 31, 2004 and 2003.

We maintain inventories of antibodies and antigens as components for our diagnostic test kits. Due to a limited shelf life on some products such as the RIA kits, finished kits are prepared as required for immediate delivery of pending and anticipated orders. Sales orders are normally processed on the day of receipt.

The principal raw materials used by Lancer in the manufacture of its products include: stainless steel, which is available from several commercial sources; nickel titanium, which is available from three sources; and lucolux translucent ceramic, which is currently only available from one source, General Electric, and is purchased on open account. Ceramic material similar to General Electric's lucolux translucent ceramic is available from other sources. Lancer

## Edgar Filing: BIOMERICA INC - Form 10KSB

had no difficulty in obtaining an adequate supply of raw materials during its 2004 fiscal year, and does not anticipate that there will be any interruption or cessation of supply in the future.

5

### COMPETITION

Immunodiagnostic products are currently produced by more than 100 companies, a majority of which are located within the United States. Biomerica is not a significant factor in the market.

Our competitors vary greatly in size. Many are divisions or subsidiaries of well-established medical and pharmaceutical concerns 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, quality of product performance, price, service and marketing. The prices for our products compare favorably with those charged by most of our competitors.

We believe we compete primarily on the basis of the uniqueness of our products, our reputation for the quality of our products, the speed of our test results, our patent position, and our prompt shipment of orders. We offer a broader range of products than many competitors of comparable size, but to date have had limited marketing capability. We are working on expanding this capability through strategic cooperation with larger companies and distributors.

Lancer encounters intense competition in the sale of orthodontic products. Lancer's management believes that Lancer's six major competitors are: Unitek, a subsidiary or division of 3M; Ormco, a subsidiary or division of Sybron Dental Specialities; RMO Inc., a private company; American Orthodontics, a private company; GAC, a division of Dentsply; and Dentaaurum, a foreign company. Lancer estimates that these six competitors account for approximately 70-80% of the orthodontic products manufactured and sold in the United States. Lancer's management also believes that each of these six competitors is larger than Lancer, has more diversified product lines and has financial resources exceeding those of Lancer. While there is no assurance that Lancer will be successful in meeting the competition of these six major competitors or other competitors, Lancer has, in the past, successfully competed in the orthodontic market and has achieved wide recognition of both its name and its products.

### GOVERNMENT REGULATION OF OUR DIAGNOSTIC BUSINESS

As part of our diagnostic business, we sell 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"), the United States Drug Enforcement Agency (the "DEA"), 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

## Edgar Filing: BIOMERICA INC - Form 10KSB

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 ensured through general controls, such as device listing, adequate labeling, pre-market notification 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 Approval ("PMA") 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 pre-market approval by the FDA pursuant to a pre-market approval application 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:

6

Class I - Fortel(TM) Ovulation test, EZ-LH(TM) Rapid Ovulation test, Strep A Rapid Test

Class II - GAP(tm) IgG H. Pylori ELISA kit, T3 EIA kit, T4 EIA kit, TSH ELISA kit, Anti-thyroglobulin ELISA kit, anti-TPO ELISA kit, PTH (intact) ELISA kit, Calcitonin ELISA kit, Erythropoietin ELISA kit, ACTH ELISA kit, Fortel Ultra Midstream (OTC and plastic stick), EZ-HCG(tm) Rapid Pregnancy test (professional and dipstick), EZ Detect(tm) Fecal Occult Blood test (Physician's dispenser pack), (professional), Aware(tm) Breast Self-Examination, drugs of abuse rapid tests, EZ-HP Professional, PTH (intact) IRMA kit, GAP(tm) IgA H. Pylori ELISA kit

Class III - GAP(tm) IgM H. Pylori ELISA kit, Professional Isletest(tm) GAD ELISA kit, Isletest(tm) ICA ELISA kit, Isletest(tm) IAA ELISA kit, Allerquant(tm) IgG Food Allergy ELISA kit, Allerquant(tm) Med90G, Allerquant(tm) 14 Foods, Custom Food Allergy Kit, Candiquant(tm) IgG ELISA kit, Candiquant(tm) IgM ELISA kit, Candiquant(tm) IgA ELISA kit, Free Alpha Subunit RIA kit, EZ-HP OTC.

If the FDA finds that the device is not substantially equivalent to a predicate device, the device is deemed a Class III device, and a manufacturer or seller is required to file a 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 requirement, 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,



## Edgar Filing: BIOMERICA INC - Form 10KSB

testing and validation activities. Further, we are required to comply with other FDA requirements with respect to labeling, and the Medical Device Reporting (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 annually. Approval of the license requires that we be in compliance with QSR, labeling and MDR regulations. Our license expires on March 16, 2005. We are also registered with the Department of Health and Human Services, Public Health Service of the FDA as a Device establishment. This registration expires on December 31, 2004. We also hold two radioactive materials licenses from the State of California (both expiring on June 20, 2008), and one permit from the USDA, expiring on August 25, 2005. 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, In Vitro Directive 98/79/EC, ISO 13485 for medical devices, and Medical Device Directive 93/42/EEC. 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.

7

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:

T3 EIA KIT  
T4 EIA KIT  
TSH ELISA KIT  
Anti-thyroglobulin ELISA kit  
Anti-TPO ELISA Kit  
GAP IgG H. Pylori ELISA Kit  
PTH(Intact) ELISA Kit  
Calcitonin ELISA Kit  
Erythropoietin ELISA Kit  
ACTH ELISA Kit  
Midstream Pregnancy Test  
EZ-HCG Rapid Pregnancy Test  
EZ-LH(tm) Rapid Ovulation Test  
EZ Detect(tm) Fecal Occult Blood Test (Physician's package, OTC package)  
Strep A Rapid Test  
AWARE(tm) Breast Self-Examination Kit  
Drugs-of-Abuse Rapid Tests

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

## Edgar Filing: BIOMERICA INC - Form 10KSB

GAP(tm) IgM H. Pylori ELISA Kit  
GAP(tm) IgA H. Pylori ELISA Kit  
PTH (intact) RIA Kit  
Isletest(tm) GAD ELISA Kit  
Isletest(tm) ICA ELISA Kit  
Isletest(tm) IAA ELISA Kit  
Allerquant(tm) IgG Food Allergy ELISA Kit (90-foods, 14-foods, custom kits)  
Candiquant(tm) IgG, IgM, and IgA ELISA Kits for Candida Albicans antibodies  
Free Alpha Subunit RIA kit  
Fortel(tm) Ultra Midstream Pregnancy Test  
Fortel(tm) Ovulation Test  
EZ-PSA Rapid Test  
EZ-H. Pylori Rapid Test

Biomerica is licensed to design, develop, manufacture and distribute IN VITRO diagnostic 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 April 2002. Biomerica is also registered and licensed with the State of California's Department of Health Services. 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 13485:2000. EN ISO 13485:2000 is an internationally recognized standard in which companies establish their methods of operation and commitment to quality.

Effective June 18, 1998, fifteen major European countries are requiring a CE (European Community) certification to sell products within their countries. The European Community Directive 98/79/EC is the IN VITRO Device Directive (IVDD), which regulates the import and sale of IN VITRO devices in the countries that comprise the European Community. In order for Biomerica's products to be sold within the European Community with the CE Mark, a Notified Body assessed Biomerica's compliance to the IVDD in October of 2003, and the Company was issued approval according to Annex IV, Article 3 of the IVDD in December 2003. Biomerica completed the translation of all direction inserts into the native languages of each of the countries in Europe where products are distributed.

Lancer is licensed to design, manufacture, and sell orthodontic appliances and is subject to the Code of Federal Regulations, Section 21, parts 800-1299. The FDA is the governing body that assesses and issues Lancer's license to assure that it complies with these regulations. Lancer is currently licensed, and its last assessment was in November 1997. Also, Lancer is registered and licensed with the state of California's Department of Health Services. The Company believes that all Lancer products sold in the U.S. comply with FDA regulations.

8

In order to obtain the CE certification Lancer retained British Standards Institution (BSI) to evaluate Lancer's quality system. Lancer's quality system is imaged under International Standards Organization (ISO) 9002. ISO 9002 is an internationally recognized standard in which companies establish their methods of operation and commitment to quality. There are 20 clauses for which Lancer has developed standard operating procedures in accordance with these ISO 9002 requirements.

EN 46002 is the medical device directive (MDD) for the European Community. Strict standards and clauses within the MDD are required to be implemented to

## Edgar Filing: BIOMERICA INC - Form 10KSB

sell within the European Community. In order for Lancer's medical devices to be sold within the European Community with the CE Mark, Lancer must fully comply with the EN 46002 requirements. Lancer has also constructed a technical file that gives all certifications and risk assessments for Lancer's products as a medical device (the "Product Technical Files").

With ISO 9002, EN 46002, and the Product Technical Files, Lancer applied for and was granted certification under ISO 9002, EN 46002, and CE. With the CE certification, Lancer is now permitted to sell its products within the European Community. Compliance with and certification to both ISO 9000:2000 and ISO 13485 was implemented in December 2003.

### SEASONALITY OF BUSINESS

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

### INTERNATIONAL BUSINESS

Most of Biomerica's fixed assets are located within southern California. The Company currently has a minor amount of fixed assets located in Mexico. Lancer has a greater number of fixed assets located there due to their larger manufacturing volume in Mexico at this time. 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 and its consolidated subsidiaries:

	Year Ended May 31,	
	2004	2003
	-----	-----
U.S. Customers	\$4,279,000/46.7%	\$4,609,000/50.9%
Asia	207,000/2.3%	228,000/2.5%
Europe	2,711,000/29.6%	2,393,000/26.4%
Middle East	311,000/3.4%	321,000/3.6%
Oceania	518,000/5.6%	452,000/5.0%
S. America	428,000/4.7%	460,000/5.1%
Other foreign	715,000/7.7%	596,000/6.5%
	-----	-----
Total Revenues	\$9,169,000/100%	\$9,059,000/100%

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. We cannot predict the impact that conversion to the Euro in the European countries may have on Biomerica or Lancer, if any.

Foreign diagnostic sales are made primarily through a network of over 100 independent distributors in approximately 50 countries.

### INTELLECTUAL PROPERTY

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

## Edgar Filing: BIOMERICA INC - Form 10KSB

copyright, trademark, 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 vendors, 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

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 January, 2002.

On April 4, 1989, Lancer was granted a patent on its Counter Force design of a nickel titanium orthodontic archwire. On August 1, 1989, Lancer was granted a patent on its bracket design used in the manufacturing of Sinterline and Intrigue orthodontic brackets. On September 17, 1996, Lancer was granted a patent on its method of laser annealing marking of orthodontic appliances. On March 4, 1997, Lancer was granted a patent on an orthodontic bracket and method of mounting. All of the patents are for a duration of 17 years. Lancer has entered into license agreements expiring in 2006 whereby, for cash consideration, the counter party has obtained the rights to manufacture and market certain products patented by Lancer. Lancer has also entered into a number of license and/or royalty agreements pursuant to which it has obtained rights to certain of the products which it manufactures and/or markets. The patents and agreements have had a favorable effect on Lancer's image in the orthodontic marketplace and Lancer's sales. Lancer has license agreements as a licensee with three products. As a licensor Lancer has licenses on the design of a nickel titanium orthodontic archwire. All but one of the agreements requires royalty payments on a percentage of net sales dollars sold over a specified period. One specific license specifies a royalty payment based upon the number of units sold.

Lancer has made a practice of selling its products under trademarks and of obtaining protection for those trademarks in the United States and certain foreign countries. Lancer considers these trademarks to be of importance in the operation of its business.

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.

### EMPLOYEES

As of August 14, 2004, the Company and its subsidiaries employed 57 full-time employees of whom 3 are part-time employees in the United States. Of the 57 employees, 33 are employees of Lancer and 24 are Biomerica employees. The number of employees between the two companies decreased over the previous year according to the following breakdown between departments:

2004	2003
----	----

## Edgar Filing: BIOMERICA INC - Form 10KSB

Administrative	9	11
Marketing & sales	16	17
Research & development	3	2
Production and operations	29	32
	--	--
Total	57	62

10

In addition, Lancer, through its Mexican subsidiary, employs approximately 102 people. Biomerica contracts with 11 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 2. DESCRIPTION OF PROPERTY

Biomerica leases its primary facility under a non-cancelable operating lease expiring October 31, 2004, with monthly lease rent of \$15,000 with a 3% increase effective September 1, 2003. The facilities are owned and operated by four of the Company's shareholders one of whom is an officer and director. During fiscal 2004 the Company consolidated some of its operations and the landlords agreed to take back the space no longer needed by the Company and to reduce the rent accordingly. The landlords also agreed not to institute the 3% increase as required in the lease. The current monthly rent is \$12,940. In May and June 2003 the Company issued 60,000 shares of Biomerica restricted common stock plus warrants to purchase an additional 60,000 shares of Biomerica restricted common stock at the purchase price of \$0.25 for payment of \$15,000 in accrued rent. Management believes there would be no significant difference in the terms of the leases if they were with a third party. Total rent expense for this facility was approximately \$150,000 and \$165,000 during the years ended May 31, 2004 and 2003, respectively.

The facilities are leased from Mrs. Ilse Sultanian and JSJ Management. Ms. Janet Moore, an officer, director and shareholder of our Company, is a partner in JSJ Management. Mrs. Ilse Sultanian and the other partners of JSJ Management, Susan Irani and Jennifer Irani, are shareholders of the Company.

At May 31, 2004, future aggregate minimum lease payments for the facilities for Biomerica areas follows:

	Years ending May 31
	-----
2005	\$169,000
2006	68,000
2007	2,000
	-----
	\$239,000

Biomerica has subleased a portion of its facility under a non-cancelable operating lease which expired May 16, 2003 and is currently month-to-month. The Company recorded base rental income of \$18,020 and \$18,062 during the years ended May 31, 2004 and 2003, respectively.

Lancer leases its main facility under a non-cancelable operating lease expiring April 30, 2009, as extended, which requires monthly rentals that increase annually, from \$6,688 per month in 2004 to \$7,527 per month in 2009. The lease expense is being recognized on a straight-line basis over the term of

## Edgar Filing: BIOMERICA INC - Form 10KSB

the lease. The excess of the expense recognized over the cash paid aggregates \$20,264 at May 31, 2004, and is included in accounts payable in the accompanying consolidated balance sheet. Total rental expense for this facility for each of the years ended May 31, 2004 and 2003 was approximately \$75,000 and \$69,000, respectively.

Effective December 1, 2002, Lancer Orthodontics de Mexico entered into a non-cancelable operating lease for its Mexico facility through March 31, 2009. The new lease encompasses the approximately 16,000 square feet of the previous lease, plus additional square footage of approximately 10,000, for a total of approximately 26,000 square feet. Lancer Orthodontics de Mexico is providing subcontracted manufacturing services to Biomerica, Inc., using a portion of the additional square footage. The lease requires monthly payments of approximately \$9,600 through March 2009. An agreement has been negotiated between Lancer Orthodontics de Mexico and Biomerica for lease reimbursement of approximately \$2,000 per month. The remainder of approximately \$7,600 monthly lease expense will be borne by Lancer. Total rent expense for this facility for the year ended May 31, 2004 and 2003, was approximately \$103,000 and \$76,000, respectively.

The Lancer Orthodontics de Mexico lease also required an additional refundable security deposit of \$26,550. Lancer Orthodontics, Inc., paid half and Biomerica, Inc. the other half. This is in addition to the \$31,146 refundable security deposit paid in fiscal year 2002. At May 31, 2004 other assets on the balance sheet include approximately \$44,000 of security deposit paid by Lancer on the Mexico location.

11

Future aggregate minimum annual cash lease payments for Lancer are as follows:

	Years ending May 31
	-----
2005	223,000
2006	225,000
2007	228,000
2008	228,000
2009	191,000
	-----
Total	\$1,095,000

A sub-lease agreement for approximately 459 square feet of Lancer's main facility as entered into in April 2003, effective through November 2003, and extended in December 2003 through November 2004. The leased space is to be used for a machine shop and requires monthly payments of \$344. Rental income for the sub-leased space for the years ended May 31, 2004 and 2003 were \$4,128 and \$344, respectively.

We believe that our facilities and equipment are in suitable condition and are adequate to satisfy the current requirements of our Company and our subsidiaries.

### CONTRACTUAL OBLIGATIONS AND COMMERCIAL COMMITMENTS

The following table summarizes the Company's obligations and commitments as of May 31, 2004:

	Payments Due by Period
Contractual Cash	Less than

## Edgar Filing: BIOMERICA INC - Form 10KSB

Obligations	Total	1 year	1-3 years	5 years
Shareholder debt	\$ 317,318	\$ 317,318	--	--
Operating Leases	\$1,355,156	397,336	\$ 537,988	\$ 419,832
<b>Total</b>	<b>\$1,672,474</b>	<b>\$ 714,654</b>	<b>\$ 537,988</b>	<b>\$ 419,832</b>

Pursuant to the terms of an employment agreement between Lancer and Dan Castner, the Vice President of Sales and Marketing for Lancer, dated May 20, 2003, Lancer agreed to pay Mr. Castner an annual base salary of \$135,000. After June 1, 2004, the contract is automatically extended on a month-to-month basis requiring fourteen days notice of intention to terminate by either party.

In addition, Lancer granted Mr. Castner stock options to purchase an aggregate of 120,000 shares of Lancer common stock at an exercise price of \$0.43 per share. The stock options have a term of five years and will vest over four years as follows: (i) 25% vesting on the first anniversary of the date of grant; (ii) 25% vesting on the second anniversary of the date of the grant; (iii) the remaining 50% vesting as to one-twenty fourth (1/24th) per month each month thereafter for the next two years. Should Lancer be purchased by an unaffiliated third party, the options shall vest 100%.

### ITEM 3. LEGAL PROCEEDINGS

---

In January 2001, ReadyScript, Inc., entered into negotiations with PacifiCare Health Systems, Inc. and its wholly owned subsidiary RxConnect Acquisition Corporation, for a transaction that would have resulted in the sale of substantially all of ReadyScript's assets or stock to PacifiCare or PacifiCare controlled entities. The transaction was seen as desirable for ReadyScript due to financing and cash flow concerns that threatened ReadyScript's ability to operate as a going concern. As part of the negotiations, the parties developed a term sheet and entered into a confidentiality and consulting agreement in connection with the proposed transaction. In March 2001, PacifiCare and RxConnect terminated negotiations and refused to close the proposed transaction. In April 2001, ReadyScript ceased doing business and filed suit against PacifiCare and Rx Connect in Orange County

12

California Superior Court alleging breach of the confidentiality and consulting agreements, misappropriation of trade secrets, unfair competition, fraud and other related claims. The court ordered the case to arbitration and in March 2004, the parties reached a confidential settlement agreement. After paying attorney's fees, all remaining proceeds will be distributed to former ReadyScript employees who were owed unpaid wages.

### ITEM 4. SUBMISSION OF MATTERS TO VOTE OF SECURITY HOLDERS

---

Inapplicable.

## PART II

### ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

---

During fiscal 2002 Biomerica's common stock was traded on the Nasdaq Small Cap system under the symbol "BMRA". Since June 20, 2002, the Company's stock has

## Edgar Filing: BIOMERICA INC - Form 10KSB

been quoted on the OTC Bulletin Board under the symbol "BMRA.OB".

Pursuant to a decision by the Nasdaq Listing Qualifications Panel, the Company's common stock was delisted from the Nasdaq Stock Market effective June 20, 2002, for failure to comply with the net tangible assets or shareholders' equity requirements as set forth in Marketplace Rule 4310(c)(2)(B). The Company's securities were immediately eligible to be quoted on the OTC Bulletin Board and are quoted under the symbol BMRA.OB.

Shares quoted on the OTC Bulletin Board are not as liquid as those traded on Nasdaq National market or the Nasdaq SmallCap market.

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, 2004.....	\$0.70	\$0.42
February 28, 2004.....	\$0.65	\$0.38
November 30, 2003.....	\$0.55	\$0.40
August 31, 2003.....	\$0.52	\$0.35
May 31, 2003.....	\$0.52	\$0.20
February 28, 2003.....	\$0.51	\$0.17
November 30, 2002.....	\$0.49	\$0.18
August 31, 2002.....	\$0.60	\$0.33

As of August 19, 2004, the number of holders of record of Biomerica's common stock was approximately 984, 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.

The following is information on issuances of securities during the past three fiscal years:

13

Date	Title	Amount	Class or Persons Sold To	Price per Share	Total
6/01	common	14,166	insiders & qualified investors	\$0.72	\$ 10,200
3/02	common	17,000	insiders & qualified investors	\$0.50	\$ 8,500
3/02	common	6,250	qualified investor	\$0.61	\$ 3,813
9/02	common	87,778	insiders & qualified investors	\$0.45	\$ 51,417



## Edgar Filing: BIOMERICA INC - Form 10KSB

2/03	common	100,000	qualified investor	\$0.25	\$ 25,000
3/03	common	98,182	insiders & qualified investors	\$0.22	\$ 21,600
5/03	common	22,107	qualified investor	\$0.45	\$ 20,611
5/03	common	60,000	insider & qualified investors	\$0.25	\$ 15,000
6/03	common	202,000	insider & qualified investors	\$0.25	\$ 50,500

The exemption relied upon for the issuance of the unregistered shares was that the shares were issued to accredited investors within the meaning of Securities and Exchange Commission Rule 501 of Regulation D.

### EQUITY COMPENSATION PLANS

The table below provides information relating to our equity compensation plans as of May 31, 2004:

Securities Plan Category	Number of Securities To be issued upon Exercise of outstanding Options	Compensations Plans Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under (Excluding Reflected in First Column)
Equity compensations Plans approved by Securities holders			
Total	928,828	\$1.02	783,123*

\* Of these shares, 628,394 have not yet been registered by a Form S-8.

### ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS

-----

EXCEPT FOR HISTORICAL INFORMATION CONTAINED HEREIN, THE STATEMENTS IN THIS FORM 10-KSB ARE FORWARD-LOOKING STATEMENTS. FORWARD-LOOKING STATEMENTS INVOLVE KNOWN AND UNKNOWN RISKS AND UNCERTAINTIES WHICH MAY CAUSE BIOMERICA'S AND LANCER'S RESULTS IN FUTURE PERIODS TO DIFFER FROM FORECASTED RESULTS. THESE RISKS AND UNCERTAINTIES INCLUDE, AMONG OTHER THINGS, THE CONTINUED DEMAND FOR THE COMPANIES' PRODUCTS, AVAILABILITY OF RAW MATERIALS AND THE STATE OF THE ECONOMY. THESE AND OTHER RISKS ARE DESCRIBED IN THE COMPANY'S ANNUAL REPORT ON FORM 10-KSB AND IN THE COMPANY'S OTHER FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION.

### LIQUIDITY AND GOING CONCERN

These consolidated financial statements have been prepared assuming that

## Edgar Filing: BIOMERICA INC - Form 10KSB

the Company will continue as a going concern. The Company has operating and liquidity concerns due to historically reporting net losses and negative cash flows from operations. Biomerica's shareholder's line of credit expired on September 13, 2003 and was not renewed. The unpaid principal and interest was converted into a note payable bearing interest at 8% and payable in September 2004.

The Company has suffered substantial recurring losses from operations over the last several years. Biomerica has funded its operations through debt and equity financings, and may have to do so in the future. ReadyScript operations were discontinued in May 2001 and Allergy Immuno Technologies, Inc. was sold in May 2002. ReadyScript and Allergy Immuno Technologies, Inc. were contributors to the Company's losses. In fiscal years 2004 and 2003, the Company reduced operating costs through certain cost reduction efforts and plans to concentrate on its core business in Lancer and Biomerica to increase sales. Management believes that cash flows from operations coupled with reduced costs and anticipated increased sales should enable the Company to fund operations for at least the next twelve months. Should the Company be unable to reduce costs or increase sales adequately or should the Company be unable to secure additional financing, the result for the Company could be the inability to continue as a going concern.

The Company will continue to have limited cash resources. Biomerica, as a parent entity, has no open or existing, operating line of credit or loans on which it can draw any debt financing and we are not currently in negotiations to obtain such financing. Although the Company's management recognizes the imminent need to secure additional financing or increase sales, there can be no assurance that the Company will be successful in consummating any such transaction or, if the Company does consummate such a transaction, that the terms and conditions of such financing will not be unfavorable to shareholders.

Our independent certified public accountants have concluded that these factors, among others, raise substantial doubt as to the Company's ability to continue as a going concern for a reasonable period of time, and have, therefore modified their report in the form of an explanatory paragraph describing the events that have given rise to this uncertainty. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

### RESULTS OF OPERATIONS

Biomerica currently has one active subsidiary, Lancer Orthodontics, Inc. ("Lancer"), which is engaged in manufacturing, sales and development of orthodontic products. We own approximately 25.0% of the outstanding stock of Lancer. Biomerica exercises effective control of over 50% over Lancer via voting agreements with some Biomerica directors and certain shareholders. As a result of our control and ownership, our financial statements are consolidated with those of Lancer. Lancer is a public company whose common stock is traded on the bulletin board system under the symbol "LANZ,".

The ReadyScript subsidiary was a development-stage enterprise and required the raising of a significant amount of capital to fund its short-term working capital needs. The ReadyScript operations were discontinued in May 2001. The sale of some of the ReadyScript intangible assets has been discussed with various parties, however at this time there is no purchaser for these assets. The subsidiary is being reported in the financial statements as a discontinued operation because it is no longer an operating entity.

Fiscal 2004 Compared to Fiscal 2003

## Edgar Filing: BIOMERICA INC - Form 10KSB

Our consolidated net sales were \$9,168,833 for fiscal 2004 compared to \$9,059,938 for fiscal 2003. This represents an increase of \$108,895, or 1.2% for fiscal 2004. Of the total consolidated net sales for fiscal 2004, \$6,024,009 is attributable to Lancer, and \$3,144,824 to Biomerica. Lancer's sales increased by \$136,111 or 2.3% over the prior fiscal year, while Biomerica showed a sales decrease of \$27,216, or 0.8%. The increase at Lancer was attributable to an increase in international sales of \$161,017, primarily in South and Central America. Domestic sales at Lancer decreased \$24,906. Lancer instituted an increase in sales prices for domestic customers in November 2003. The decrease in sales at Biomerica was due to decreased OTC sales due to fewer EZ Detect screening programs.

15

Cost of sales in fiscal 2004 as compared to fiscal 2003 increased by \$90,932 or 1.5%. Lancer's cost of sales as a percentage of sales decreased from 70.3% to 68.5% in fiscal 2004 as compared to fiscal 2003. The decrease was primarily attributable to the selling price increase. Biomerica had an increase in cost of sales as a percentage of sales from 63.6% to 68.7% in fiscal 2004 as compared to fiscal 2003. The increase was due to increased costs related to obtaining the CE Mark and establishing the Mexicali facility.

Selling, general and administrative costs increased in fiscal 2004 as compared to fiscal 2003 by \$113,078 or 3.9%. Lancer had an increase of \$195,381 in these costs due to selling labor and advertising expenses and increased insurance and professional fees in the administrative area. Biomerica had a decrease in fiscal 2004 as compared to fiscal 2003 of \$82,303, primarily due to lower administrative wages and sales commissions.

Research and development expense increased in fiscal 2004 as compared to fiscal 2003 by \$11,140 or 4.2%. Of this, Lancer had an increase of \$8,734, as a result of increased labor costs associated with development of new products and manufacturing technologies. Biomerica had an increase in research and development expenses of \$2,406.

Interest expense net of interest income, increased in fiscal 2004 as compared to fiscal 2003 by \$1,847 or 5.7%, due to an decrease of such expense at Lancer of \$1,729 which was offset by an increase at Biomerica of \$3,576 due to interest due on the note payable shareholder and rent payable.

Other income increased by \$9,513 or 1.4% in fiscal 2004 as compared to fiscal 2003. Of this, Lancer had an increase in other income of \$7,401 due to an increase in income from providing shelter services in Mexico and rental income, offset by the decrease in income due to insurance proceeds received in 2003. Lancer had rental income of \$4,128 in fiscal year 2004 resulting from the sub-lease of approximately 459 square feet of San Marcos warehouse space. Biomerica had increases in other income of \$2,112.

As of May 31, 2004 Biomerica had net tax operating loss carryforwards of approximately \$4,607,000 and investment tax and research and development credits of approximately \$62,000, which are available to offset future federal tax liabilities. These carryforwards expire at varying dates from 2003 to 2023. As of May 31, 2004, Biomerica had net operating tax loss carryforwards of approximately \$1,289,000 available to offset future state income tax liabilities, which expire through 2012. As of May 31, 2004, Lancer had net operating loss carryforwards of approximately \$1,997,000 and business tax credits of approximately \$63,000 available to offset future Federal tax liabilities. The Lancer federal carryforwards expire through 2021. As of May 31, 2004, Lancer had net tax operating loss carryforwards of approximately \$70,000 and business tax credits of approximately \$10,000 available to offset future state income tax liabilities. The state carryforwards expire through the year

## Edgar Filing: BIOMERICA INC - Form 10KSB

2013.

### Liquidity, Capital Resources and Going Concern

As of May 31, 2004, we had cash and available for sale securities of \$378,494 (see Note 2 of Notes to Consolidated Financial Statements) and current working capital of \$2,696,065. Of the current working capital, \$2,822,792 is attributable to the Lancer subsidiary, which is restricted from distribution of any assets (except for reimbursement of expenses on behalf of Lancer or for services rendered for Biomerica). During 2004, cash used in operations was \$75,032 as compared to cash provided by operations in fiscal 2003 of \$512,536. During fiscal 2004, cash used in investing activities was \$390,122, primarily due to the purchase of property and equipment at Lancer of \$394,612 which was offset by sales of available for sale securities at Biomerica of \$45,967. During fiscal 2003 cash used in investing activities was \$239,285 primarily due to the purchase of property and equipment at Lancer. During 2004, cash provided by financing activities of \$293,335 was primarily a result of sale of common stock of \$270,000 at Lancer and \$50,500 at Biomerica. During 2003, cash used in financing activities was \$74,548 due to decreases in borrowings.

On an unconsolidated basis, Biomerica used cash in operating activities of \$24,336 in fiscal 2004 as compared to \$126,954 in fiscal 2003. Net cash provided by (used in) investing activities for the years ended May 31, 2004 and 2003 were \$3,937 and (\$38,528), respectively. Net cash provided by and (used in) financing activities was \$54,868 for fiscal 2004 and (\$21,450) for fiscal 2003. See Note 11 to the Notes to Consolidated Financial Statements.

16

These consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has operating and liquidity concerns due to historically reporting net losses and negative cash flows from operations. Biomerica's shareholder's line of credit expired on September 13, 2003 and was not renewed. The unpaid principal and interest was converted into a note payable bearing interest at 8% and payable September 1, 2004.

The Company has suffered substantial recurring losses from operations over the last several years. Biomerica has funded its operations through debt and equity financings, and may have to do so in the future. ReadyScript operations were discontinued in May 2001 and Allergy Immuno Technologies, Inc. was sold in May 2002. ReadyScript and Allergy Immuno Technologies, Inc. were major contributors to the Company's losses. In the fiscal years 2003 and 2004, the Company reduced operating costs through certain cost reduction efforts and concentrated on its core business in Lancer and Biomerica to increase sales.

Management believes that cash flows from operations coupled with reduced costs and anticipated increased sales should enable the Company to fund operations for at least the next twelve months. Should the Company be unable to reduce costs or increase sales adequately, or should the Company be unable to secure additional financing, the result for the Company could be the inability to continue as a going concern.

The Company will continue to have limited cash resources. Biomerica, as a parent entity, has no open or existing, operating line of credit or loans on which it can draw any debt financing and we are not currently in negotiations to obtain such financing. Although the Company's management recognizes the imminent need to secure additional financing or increase sales, there can be no assurance that the Company will be successful in doing so or, if the Company does consummate such a financing, that the terms and conditions of such financing will not be unfavorable to shareholders.

## Edgar Filing: BIOMERICA INC - Form 10KSB

Our independent certified public accountants have concluded that these factors, among others, raise substantial doubt as to the Company's ability to continue as a going concern for a reasonable period of time, and have, therefore modified their report in the form of an explanatory paragraph describing the events that have given rise to this uncertainty. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

During fiscal 2004 Lancer management negotiated a new line of credit with Cuyamaca Bank through January 8, 2005. The line of credit allows for borrowings up to \$400,000 and are limited to 80% of accounts receivable less than 90 days old. The outstanding balance at May 31, 2004 was \$0 and the unused portion available under the line of credit at May 31, 2004, was approximately \$340,000. Borrowings bear interest at prime plus 2.00% per annum, but not lower than 8% (6.% at May 31, 2004). Lancer requested that Cuyamaca Bank reserve \$60,000 of Lancer's available credit as a guarantee of credit with a European supplier.

The Lancer line of credit is collateralized by substantially all the assets of Lancer, including inventories, receivables, and equipment. The lending agreement for the line of credit requires, among other things, that Lancer maintain a tangible net worth ratio of \$2,700,000, and that a zero outstanding balance be maintained for 30 consecutive days during the term. The line of credit expires on January 8, 2005.

Lancer also had a term loan for \$100,000 with Cuyamaca Bank that was paid off in May 2004. This loan required monthly payments of approximately \$2,300 (principal and interest) at an interest rate of prime plus 2% (6% at May 31, 2004).

Lancer is restricted from distribution of any assets to Biomerica except for reimbursement of expenses on behalf of Lancer or for services rendered.

Lancer's management believes that it will be able to finance Lancer's operations through cash flow and available borrowings through the current fiscal year and ensuing fiscal years based upon a level of demand for their products approximately consistent or in excess of prior years.

17

Biomerica, Inc. entered into an agreement for a line of credit agreement on September 12, 2000 with a shareholder whereby the shareholder would loan to the Company, as needed, up to \$500,000 for working capital needs. The line of credit bore interest at 8%, was secured by accounts receivable and inventory, and expired September 13, 2003. In March 2004 the Company signed a note payable for the principal and interest due at that time of \$313,318 and agreed to a forbearance of any payments for the length of the agreement. A warrant for 40,000 shares of restricted common stock exercisable at a price of \$.51 per share was awarded as compensation for the forbearance. The note payable is secured by all of the Company's assets except for the Lancer common stock owned by Biomerica. The note is due September 1, 2004. There was \$313,318 of outstanding principal and \$5,356 of interest payable under this note payable at May 31, 2004 (also see Note 7).

During 2004 and 2003, a shareholder advanced the Company \$4,000 and \$10,000, respectively. During June 2003 the \$10,000 advance was repaid in the form of Company common stock at the price of \$.25 per share. Interest for the fiscal year ended May 31, 2004 was \$283. At May 31, 2004, \$1,555 was owed in interest payable on the two loans.

## Edgar Filing: BIOMERICA INC - Form 10KSB

During 2004 and 2003, the Company incurred \$32,060 and \$29,466, respectively, in interest expense related to the shareholder line of credit, note payable and rental liabilities, of which \$19,200 was paid in fiscal 2004. As of May 31, 2004, \$12,860 in accrued interest was due on the promissory note and rental liabilities.

Pursuant to a decision by the Nasdaq Listing Qualifications Panel, the Company's common stock was delisted from the Nasdaq Stock Market effective June 20, 2002, for failure to comply with the net tangible assets or shareholders' equity requirements as set forth in Marketplace Rule 310(c)(2)(B). The Company's securities were immediately eligible to trade on The OTC Bulletin Board and are traded under the symbol BMRA.

### 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. Note 2 of the Notes to 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.

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. Although we believe that our judgments and estimates are appropriate and correct, actual future results may differ from our estimates.

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.

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 for estimated returns as revenue is recognized.

The 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 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

## Edgar Filing: BIOMERICA INC - Form 10KSB

in subsequent periods we forecast demand for the product.

In general, we are in a loss position for tax purposes, and have established a valuation allowance against deferred tax assets, as we do not believe it is likely that we will generate sufficient taxable income in future periods to realize the benefit of our deferred tax assets. Predicting future taxable income is difficult, and requires the use of significant judgment. At May 31, 2004, all of our deferred tax assets were reserved. Accruals are made for specific tax exposures and are generally not material to our operating results or financial position, nor do we anticipate material changes to these reserves in the near future.

### 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 SEC 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 fiscal year 2002, 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 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; the operating and financial covenants contained in our credit line and Lancer's which could limit our operating flexibility; 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 dental 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.

### INSURANCE COVERAGE

Biomerica currently carries various insurance policies including products liability (\$2,000,000), general liability (\$2,000,000), property insurance (premises-\$2,589,350 and personal property-\$1,622,400), business income insurance (\$800,000), employee benefit liability insurance (\$1,000,000), commercial crime insurance (\$100,000), crime insurance (pension plan) (\$300,000), employee theft (\$100,000), depositor's forgery (\$100,000), commercial auto (\$1,000,000) umbrella liability insurance (\$1,000,000), workman's compensation insurance (\$1,000,000), directors and officers' insurance (\$2,000,000), group health, disability and life insurance. Lancer currently has coverage for personal property (\$472,500), business income (\$1,200,000), general liability (\$2,000,000), employee benefit liability (\$1,000,000), products

## Edgar Filing: BIOMERICA INC - Form 10KSB

liability (\$2,000,000), auto (\$1,000,000), commercial fidelity (\$100,000), difference in conditions and Mexico required coverage (\$2,500,000), directors and officers' insurance (shared with Biomerica) (\$2,000,000); group health and dental. Both Lancer's and Biomerica's workman's compensation policies cover injuries to employees as a result of accidental contamination of hazardous materials. The companies do not have a separate policy for contamination of hazardous materials.

19

### RECENT ACCOUNTING PRONOUNCEMENTS:

In October 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144 ("SFAS No. 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 requires that those long-lived assets be measured at the lower of carrying amount or fair value less cost to sell, whether reported in continuing operations or in discontinued operations. Therefore, discontinued operations will no longer be measured at net realizable value or include amounts for operating losses that have not yet occurred. SFAS No. 144 is effective for financial statements issued for fiscal years beginning after December 15, 2001 and, generally, is to be applied prospectively. This standard was effective for the Company's consolidated financial statements beginning June 1, 2002. The implementation of SFAS No. 144 did not have a material impact on the Company's consolidated financial position or results of operations.

In April 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 145 ("SFAS No. 145"), "Rescission of SFAS No. 44 and 64, Amendment of SFAS No. 13, and Technical Corrections," to update, clarify and simplify existing accounting pronouncements. SFAS No. 4, which required all gains and losses from debt extinguishment to be aggregated and, if material, classified as an extraordinary item, net of related tax effect, was rescinded. Consequently, SFAS No. 64, which amended SFAS No. 4, was rescinded because it was no longer necessary. The adoption of this statement did not have a material effect on the Company's consolidated financial position or results of operations.

In June 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 146 ("SFAS No. 146"), "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 addresses accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (Including Certain Costs Incurred in a Restructuring)." SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized and measured initially at fair value when the liability is incurred. SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The adoption of this statement did not have a material effect on the Company's consolidated financial position or results of operations.

In December 2002, the Financial Accounting Standards Board issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an Amendment of FASB Statement No. 123." This statement amends SFAS No. 123, "Accounting for Stock-Based Compensation", to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this statement amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The Company adopted the disclosure requirements effective December 1,



## Edgar Filing: BIOMERICA INC - Form 10KSB

2002, in its consolidated financial statements. The adoption of SFAS No. 123 did not have a material effect on the Company's consolidated financial position or results of operations.

In November 2002, FIN No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others," was issued. FIN 45 requires that upon issuance of a guarantee, a guarantor must recognize a liability for the fair value of an obligation assumed under a guarantee. FIN 45 also requires additional disclosures by a guarantor in its interim and annual financial statements about the obligations associated with guarantees issued. The recognition provisions of FIN 45 are effective for guarantees issued after December 31, 2002, while the disclosure requirements were effective for financial statements for periods ending after December 15, 2002. The adoption of FIN 45 did not have a material impact on the Company's consolidated financial position or results of operations.

In January 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46 ("FIN No. 46"), "Consolidation of Variable Interest Entities". In December 2003, FIN 46 was replaced by FASB Interpretation No. 46R, "Consolidation of Variable Interest Entities." FIN 46R clarifies some of the provisions of FIN 46 and exempts certain entities from its requirements. FIN 46R was effective at the end of the first interim period ending March 15, 2004.

20

Entities that have adopted FIN 46 prior to this date can continue to apply provisions of FIN 46 until the effective date of FIN 46R or early election of FIN 46R. This interpretation clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," relating to consolidation of certain entities. FIN No. 46 requires identification of the Company's participation in variable interests entities ("VIEs"), which are defined as entities with a level of invested equity that is not sufficient to fund future activities to permit them to operate on a stand-alone basis, or whose equity holders lack certain characteristics of a controlling financial interest. For entities identified as VIEs, FIN No. 46 sets forth a model to evaluate potential consolidation based on an assessment of which party to the VIE, if any, bears a majority of the exposure to its expected losses, or stands to gain from a majority of its expected returns. FIN No. 46 also sets forth certain disclosures regarding interests in VIE that are deemed significant, even if consolidation is not required. The adoption of FIN No. 46 did not have a material impact on the Company's financial position or results of operations.

In April 2003, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 149 ("SFAS No. 149"), "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." This statement amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities." This statement is effective for contracts entered into or modified after June 30, 2003. The adoption of this statement did not have a significant effect on the Company's consolidated financial position or results of operations.

In May 2003, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 150 ("SFAS No. 150"), "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 provides guidance on how an entity classifies and measures certain financial instruments with characteristics of both liabilities and equity. Many of these instruments were previously classified as equity. This statement is

## Edgar Filing: BIOMERICA INC - Form 10KSB

effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The statement requires cumulative effect transition for financial instruments existing at the adoption date. The adoption of this statement did not have a material effect on the Company's consolidated financial position or results of operations.

### ITEM 7. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

---

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

### ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

---

The Company's independent auditors for the fiscal years ended May 31, 2003 and 2002 were BDO Seidman, LLP ("BDO"). Effective May 29, 2004, the Company, upon approval of the audit committee of the Board of Directors of the Company, dismissed BDO. Effective May 29, 2004 the Company, upon approval of the audit committee of the Board of Directors, approved the appointment of PKF, Certified Public Accountants, A Professional Corporation, San Diego, as the Company's independent auditors for the fiscal year ended May 31, 2004.

BDO last reported on the Company's financial statements on August 11, 2003. The report, which covered the two fiscal years ended May 31, 2003, was modified for going concern. BDO expressed substantial doubt as to the Company's ability to remain a going concern.

The auditors' report of BDO Seidman on the consolidated financial Statements of Biomerica, Inc. and subsidiaries as of and for the years ended May 31, 2003 and 2002 contained the following paragraph:

21

"The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has historically reported net losses and negative cash flows from operations, which raise serious liquidity concerns. Management estimates that its available cash resources as of May 31, 2003 along with cost reductions will be sufficient to fund planned operations through May 31, 2004. These operating and liquidity issues, amongst other concerns, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 1 to the accompanying consolidated financial statements. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern."

The change of independent accountants was ratified by the Board of Directors of the Company on May 29, 2004.

During the two fiscal years ended May 31, 2003 and the subsequent interim period through May 29, 2004, there were no disagreements between the Company and BDO on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which, if not resolved, to BDO's satisfaction, would have caused it to make reference to the subject matter of the disagreement in connection with its report.

During and the two fiscal years ended May 31, 2003 and subsequent interim

## Edgar Filing: BIOMERICA INC - Form 10KSB

period through May 29, 2004, there have been no reportable events (as defined in Regulation S-K Item 304(a)(1)(v)).

During the two fiscal years ended May 31, 2003 and the subsequent interim period through May 29, 2004 BDO did not advise the Company that the internal controls necessary for the Company to develop reliable financial statements do not exist.

During the two fiscal years ended May 31, 2003 and the subsequent interim period through May 29, 2004, BDO did not advise the Company that any information had come to their attention which had led them to no longer be able to rely on management's representation, or that had made BDO unwilling to be associated with the financial statements prepared by management.

During the two fiscal years ended May 31, 2003 and the subsequent interim period through May 29, 2004, BDO did not advise the Company that the scope of any audit needed to be expanded significantly or that more investigation was necessary.

During the two fiscal years ended May 31, 2003 and the subsequent Interim period through May 29, 2004, BDO did not advise the Company that There was any information which the accountants concluded would materially Impact the fairness and reliability of either (i) a previously issued Audit report or the underlying statements, or (ii) the financial statements Issued or to be issued covering the fiscal period(s) subsequent to the Date of the most recent financial statements covered by an audit report (including information that, unless resolved to the accountant's satisfaction, would prevent it from rendering an unqualified audit report on those financial statements).

The Company engaged PKF, Certified Public Accountants, A Professional Corporation (San Diego) ("PKF") as its new independent accountant on May 29, 2004. Prior to May 29, 2004, the Company had not consulted with PKF regarding (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and no written report or oral advice was provided to the Company by PKF concluding there was an important factor to be considered by the Company in reaching a decision as to an accounting, auditing or financials reporting issue; or (ii) any matter that was either the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K, or a reportable event, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K.

22

### ITEM 8A. Controls and Procedures

-----

The Company maintains a system of disclosure controls and procedures which are designed to ensure that information required to be disclosed by the Company in the reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported with the time period specified under the Securities and Exchange Commission's rules and forms. Based on an evaluation performed, the Company's certifying officers have concluded that the disclosure controls and procedures were effective as of the end of the period covered by this report to provide reasonable assurance of the achievement of these objectives.

Notwithstanding the foregoing, there can be no assurance that the Company's disclosure controls and procedures will detect or uncover all failures of persons within the Company to disclose material information otherwise required to be set forth in the Company's reports.

Edgar Filing: BIOMERICA INC - Form 10KSB

We do not believe that there has been any change in the Company's internal control over financial reporting during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT.  
-----

This information is incorporated by reference to the Company's proxy statement for its 2004 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, 2004.

ITEM 10. EXECUTIVE COMPENSATION  
-----

This information is incorporated by reference to the Company's proxy statement for its 2004 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, 2004.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT  
-----

This information is incorporated by reference to the Company's proxy statement for its 2004 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, 2004.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS  
-----

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, 2004, Biomerica has paid all applicable shelter fees.

Other information regarding related transactions is incorporated by reference to the Company's proxy statement for its 2004 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, 2004.

23

ITEM 13. EXHIBITS LIST AND REPORTS ON FORM 8-K  
-----

(a) EXHIBITS  
-----

EXHIBIT NO.	DESCRIPTION
-------------	-------------

## Edgar Filing: BIOMERICA INC - Form 10KSB

- 
- 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).
  - 10.2 Lancer purchase agreement and warrants (incorporated by reference to Exhibit 10.10 filed with Registrant's Annual Report on Form 10-K for the fiscal year ended May 31, 1989).
  - 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).

## Edgar Filing: BIOMERICA INC - Form 10KSB

- 10.4 1995 Stock Option and Common Stock Plan of Registrant (incorporated by reference to Exhibit 4.3 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on January 20, 1996).
- 24
- 10.5 1991 Stock Option and Restricted Stock Plan of Registrant (incorporated by reference to Exhibit 4.1 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on April 6, 1992).
- 10.6 Stock Purchase Agreement by and between Biomerica, Inc., RidgeRose Capital Partners, LLC and Zackary Irani and Janet Moore dated June 11, 1999 (incorporated by reference to Exhibit 10.10 filed with Form 8-K on July 7, 1999).
- 10.7 Stock Purchase Agreement by and between Biomerica, Inc. and Zackary Irani and Janet Moore dated June 11, 1999 (incorporated by reference to Exhibit 10.11 filed with Form 8-K on July 7, 1999).
- 10.8 Back-end Processing Agreement by and between TheBigStore.com, Inc. and Biomerica, Inc. and dated June 11, 1999 (incorporated by reference to Exhibit 10.12 filed with Form 8-K on July 7, 1999).
- 10.9 Common Stock Purchase Warrant granted to TheBigStore.com, Inc. dated June 11, 1999 (incorporated by reference to Exhibit 10.13 filed with Form 8-K on July 7, 1999).
- 10.10 Common Stock Purchase Warrant granted to RJM Consulting, LLC dated June 11, 1999 (incorporated by reference to Exhibit 10.14 filed with Form 8-K on July 7, 1999).
- 10.11 Non-Qualified Option Agreement by and between Zackary Irani and the Company dated June 10, 1999 (incorporated by reference to Exhibit 10.15 filed with Form 8-K on July 7, 1999).
- 10.12 Non-Qualified Option Agreement by and between Janet Moore and the Company dated June 10, 1999 (incorporated by reference to Exhibit 10.16 filed with Form 8-K on July 7, 1999).
- 10.13 Non-Qualified Option Agreement by and between Philip Kaplan, M.D. and the Company dated June 10, 1999 (incorporated by reference to Exhibit 10.17 filed with Form 8-K on July 7, 1999).
- 10.14 Non-Qualified Option Agreement by and between Robert A. Orlando, M.D., Ph.D. and the Company dated June 10, 1999 (incorporated by reference to Exhibit 10.18 filed Form 8-K on July 7, 1999).
- 10.15 Strategic Marketing Agreement entered into as of the 2nd day of September, 1999 by and between TheBigHub.com, Inc., a Florida corporation and Biomerica, Inc. (incorporated by reference to Exhibit 10.16 filed with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).
- 10.16 First Amendment to Back-End Processing Agreement entered into as of September 2, 1999 whereby TheBigStore.com, Inc., a Delaware corporation and Biomerica amend the Back-End Agreement dated June 11, 1999 (incorporated by reference to Exhibit 10.17 filed

## Edgar Filing: BIOMERICA INC - Form 10KSB

with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).

- 10.17 Private Placement Memorandum of Biomerica, Inc. dated June 9, 1999 offering 400,000 shares of its Common Stock at \$5.00 per share (incorporated by reference to Exhibit 10.18 filed with Registrant's Registration Statement on Form SB-2, Commission o. 333-87231 filed on September 16, 1999).
- 10.18 Employment Agreement entered into as of August 30, 1999 by and between the Internet division of Biomerica, Inc. and Steven J. Goto (incorporated by reference to Exhibit 10.19 filed with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).
- 10.19 Employment Offer Letter dated August 12, 1999 from Biomerica, Inc. to Pete McKinley to join the Internet division of Biomerica, Inc. (incorporated by reference to Exhibit 10.20 filed with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).

25

- 10.20 Employment Offer Letter dated August 12, 1999 from Biomerica, Inc. to Richard Jay, Pharm.D. to join the Internet division of Biomerica, Inc. (incorporated by reference to Exhibit 10.21 filed with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).
- 10.21 Amendment to Lease Extension/Lease Term effective January 1, 1999, whereby Lancer Orthodontics, Inc. and L&T Corporation, a California corporation entered into an amendment and extension to the terms of that certain lease agreement dated November 4, 1993 for the premises located at 253 Pawnee Street, Suite A, San Marcos, California 92069 (incorporated by reference to Exhibit 10.22 filed with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).
- 10.22 Sublease Agreement entered into by and between Eagleson de California S.A. de C.V. and Lancer Orthodontics, Inc. commencing on November 1, 1998 covering approximately 16,000 square feet located in the Industrial Park at Ave. Saturno No. 20 and of certain improvements constructed on the land as detailed in that certain sublease between the parties dated April 1, 1996 (incorporated by reference to Exhibit 10.23 filed with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).
- 10.23 Fifth Revision to Manufacturing Shelter Agreement effective November 1, 1998, whereby Lancer Orthodontics, Inc. and Eagleson Industries, Inc. revised and amended that certain Manufacturing Shelter Agreement entered into on May 11, 1990, revised on June 20, 1991, December 2, 1992, July 1, 1994 and April 1, 1996 (incorporated by reference to Exhibit 10.24 Filed with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).
- 10.24 Technical Skills Consulting Agreement entered into on January 1, 1999 by and between Lancer Orthodontics, Inc. and Alejandro Carnero, a non-resident alien, independent contractor and citizen of the Republic of Mexico (incorporated by reference to

## Edgar Filing: BIOMERICA INC - Form 10KSB

Exhibit 10.25 filed with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).

- 10.25 Product Development and Marketing Agreement entered into as of August 3, 1998 by and between Lancer Orthodontics, Inc. and AG Metals, Inc., a Nevada corporation (incorporated by reference to Exhibit 10.26 filed with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).
- 10.26 Agreement between Lancer Orthodontics, Inc. and Gary Weikel, an individual, incorporating by reference that certain Product Development and Marketing Agreement of even date between Lancer Orthodontics, Inc. and AG Metals, Inc. (incorporated by reference to Exhibit 10.27 filed with Registrant's Registration Statement on Form SB-2, Commission No. 333-87231 filed on September 16, 1999).
- 10.27 Lease between Biomerica, Inc., JSJ Management and Ilse Sultanian dated September 1, 2001. (Incorporated by reference to the Company's 2002 Form 10KSB/A filed June 6, 2003.)
- 10.28 Agreement between Biomerica, Inc. and Lancer Orthodontics, Inc. for the acquisition of the remaining outstanding shares of Lancer Orthodontics, Inc., common stock by Biomerica (incorporated by reference to an exhibit filed with the S-4 filed on April 10, 2002).
- 10.29 General Assignment of Assets Agreement with Allergy Immuno Technologies, Inc. (incorporated by reference to the Company 2002 Form 10KSB/A filed June 6, 2003.)
- 10.30 Asset Purchase Agreement by and between Biomerica, Inc., and Sangui Bio Tech, Inc. dated September 12, 2002.
- 26
- 10.31 Loan Modification, Forbearance and Security Agreement (incorporated by reference to the Company's February 29, 2004 Form 10-QSB filed April 14, 2004).
- 10.32 Promissory Note (incorporated by reference to the Company's February 29, 2004 Form 10-QSB filed April 14, 2004).
- 16.1 Letter on Change of Certifying Accountant (incorporated by reference to Exhibit A to Form 8-K filed with the Securities and Exchange Commission on May 24, 1993).
- 16.2 Letter on change of certifying accountant (incorporated by reference to Exhibit A to Form 10-QSB/A filed with the Securities and Exchange Commission on April 14, 1999).
- 16.3 Letter on change of certifying accountant (incorporated by reference to Exhibit A to Form 10-QSB/A filed with the Securities and Exchange Commission on April 14, 1999).
- 16.4 Letter on change of certifying accountant (incorporated by reference to Exhibit A to Form 8-K/A filed with the Securities and Exchange Commission on June 7, 2004.)



## Edgar Filing: BIOMERICA INC - Form 10KSB

- 21.1 Subsidiaries of Registrant (incorporated by reference to Exhibit 21.1 to Form 10-KSB filed with the Securities and Exchange Commission on September 14, 1999).
- 23.1 Consent of Independent Registered Public Accounting Firm (BDO Seidman, LLP)
- 23.2 Consent of Independent Registered Public Accounting Firm (PKF San Diego)
- 31.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 99.3 Biomerica, Inc. and Subsidiaries Consolidated Financial Statements For The Years Ended May 31, 2004 and 2003 and Independent Registered Public Accounting Firm' Report.

(b) Reports on Form 8-K  
-----

No reports on Form 8-K were filed in the year ended May 31, 2004. Biomerica filed a report on Form 8-K/A with the Securities and Exchange Commission on June 7, 2004. Lancer filed a report on Form 8-K June 8, 2004. Both reports were filed to report a change in independent accountants.

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

For the year end May 31, 2003, BDO Seidman, LLP audited the Company's consolidated financial statements and provided tax related services. For the interim periods for the year ended May 31, 2004, BDO Seidman, LLP performed reviews of the Form-10QSB's. PKF (San Diego), Certified Public Accountants, was engaged to audit the consolidated financial statements for the year ended May 31, 2004.

The aggregate fees billed for professional services by BDO Seidman, LLP and PKF (San Diego) in 2004 and 2003 were as follows:

	2004 ----	2003 ----
PKF audit fees	\$57,000 (1)	--
BDO audit fees	66,421 (2)	\$94,500 (3)
audit related fees	260	10,700
tax fees	--	5,274 (4)
	-----	-----

Edgar Filing: BIOMERICA INC - Form 10KSB

total \$123,681 \$110,474

- (1) Billed or to be billed in fiscal 2005.
(2) Includes \$19,000 billed in fiscal 2005 and \$47,421 billed in fiscal 2004
(3) Includes \$59,900 billed in fiscal 2004 and \$34,600 billed in fiscal 2004
(4) Billed in fiscal 2004

AUDIT FEES consist of the aggregate fees billed for professional services rendered for the audit of our annual financial statements, the audit of our subsidiaries financial statements, the reviews of the financial statements included in our Forms 10-QSB, the reviews of the financial statement included in our subsidiaries Form 10-QSB and for any other services that are normally provided by PKF or BDO in connection with our statutory and regulatory filings or engagements.

AUDIT RELATED FEES consist of the aggregate fees billed for professional services rendered for assurance and related services that were reasonably related to the performance of the audit or review of our financial statements and the financial statements of our subsidiaries that were not otherwise included in Audit Fees.

TAX FEES consist of the aggregate fees billed for professional services rendered for tax compliance, tax advice and tax planning. Included in such Tax Fees were fees for preparation of our tax returns and consultancy and advice on other tax planning matters.

ALL OTHER FEES consist of the aggregate fees billed for products and services provided by PKF or BDO and not otherwise included in Audit Fees, Audit Related fees or Tax Fees. Included in such Other Fees were fees for services rendered by PKF or BDO in connection with our private and public offerings conducted during such periods.

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: 9/9/04

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

Signature and Capacity

/s/ Zackary S. Irani

Date: 9/9/04

Edgar Filing: BIOMERICA INC - Form 10KSB

Zackary S. Irani  
President, Director, Chief Executive  
Officer

/s/ Janet Moore

Date: 9/9/04

-----  
Janet Moore, Secretary  
Director, Chief Financial Officer

/s/ Robert Orlando

Date: 9/9/04

-----  
Robert Orlando, M.D., Ph.D.  
Director

/s/ Francis R. Cano

Date: 9/9/04

-----  
Francis R. Cano  
Director

/s/ Allen Barbieri

Date: 9/9/04

-----  
Allen Barbieri  
Director