

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2011

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 333-146182

**BIOZONE PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation  
or  
organization)

20-5978559

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

550 Sylvan Avenue  
Suite 101

Englewood Cliffs, NJ

(Address of principal executive offices)

07632

(Zip Code)

Registrant's telephone number, including area code **(201) 608-5101**

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of the Company's most recently completed second fiscal quarter was approximately \$63,998,337.

As of April 16, 2012, there were 56,481,165 shares of Common Stock, par value \$0.001 per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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**BIOZONE PHARMACEUTICALS, INC.**

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## PART I

### Forward-Looking Statements

This Annual report contains forward-looking statements. Such statements include statements regarding our expectations, hopes, beliefs or intentions regarding the future, including but not limited to statements regarding our market, strategy, competition, development plans (including acquisitions and expansion), financing, revenues, operations, and compliance with applicable laws. Forward-looking statements involve certain risks and uncertainties, and actual results may differ materially from those discussed in any such statement. Factors that could cause actual results to differ materially from such forward-looking statements include the risks described in greater detail in the following paragraphs. All forward-looking statements in this document are made as of the date hereof, based on information available to us as of the date hereof, and we assume no obligation to update any forward-looking statement. Market data used throughout this Report is based on published third party reports or the good faith estimates of management, which estimates are based upon their review of internal surveys, independent industry publications and other publicly available information. Although we believe that such sources are reliable, we do not guarantee the accuracy or completeness of this information, and we have not independently verified such information.

### Item 1. Business.

#### Overview – Primary Business

Biozone Pharmaceuticals, Inc. (“Biozone Pharma”, the “Company” or “we”), through its wholly owned subsidiary, BioZone Laboratories, Inc. (“Biozone Labs”), primarily is engaged in the business of developing and manufacturing Over the Counter (“OTC”) drug products and cosmetic and beauty products on behalf of third parties. In addition, through its wholly owned subsidiaries, Equalan LLC (“Equalan”) and Baker Cummins Corp. (“Baker Cummins”) the Company markets two lines of proprietary skin care products, under the brand names of Glyderm® and Baker Cummins®, respectively. The Company’s other activities include the sale by its wholly owned subsidiary, Equachem LLC (“Equachem”) of raw materials used in OTC drugs and cosmetic products, and the research and development of certain proprietary drug delivery technology, designed to increase the benefit of various generic pharmaceutical products by improving stability, bioavailability or absorption. These activities, including in particular, the research and development of our proprietary drug delivery technology (“DDT”), are not material to the Company’s business, financial condition or results of operation. Our DDT research and development activities are in an early stage, having commenced during the year ended December 31, 2011, and have yet to generate a delivery agent that has been tested in combination with any drug in animals or humans under testing standards required by the US Food and Drug Administration (“FDA”) for submission for approval. In addition, more than 95% of the Company’s annual revenue for the years ended December 31, 2011 and 2010 and investment in property plant and equipment is related to the Company’s OTC drug product and cosmetic and beauty product manufacturing business. The Company generated \$12.6 million and \$15.3 million of sales during the years ended December 31, 2011 and 2010, respectively, of which \$11.6 million or 92% and \$13.6 million or 89%, respectively, were generated by BioZone Labs from its third party contract manufacturing business. The Company operates under a single segment.

BioZone Labs is registered with the FDA as a drug manufacturer. We manufacture OTC drug and cosmetic products in a 20,000 s.f., certified good manufacturing practice (“cGMP”) facility located at 580 Garcia Avenue, Pittsburg, CA. We fill, package and store these products at a 60,000 sq. ft. packaging and warehouse facility located at 701 Willow Pass Road, Pittsburg, CA. We maintain a full range of high to moderate speed filling and packaging equipment, capable of filling jars, tubes, and bottles with creams, lotions, oral solutions and serums. We employ scientists and chemists for product development, processing and testing, and quality control & assurance professionals for monitoring compliance with government regulations and adherence to customer specifications. Primarily, our customers are United States regional and national distributors and retailers of healthcare products.

The Company owns a 45% interest in BetaZone Laboratories LLC (“BetaZone”) which is engaged in the development, sale and license of pharmaceutical and cosmetic products in Latin America. Equachem licenses the Company’s proprietary QuSome™ technology to BetaZone and other pharmaceutical manufacturers in exchange for sales based royalties. BetaZone has yet to pay any material royalties to Equachem as it has yet to generate any significant sales or license payments from products using our licensed technology. Royalties from other pharmaceutical manufacturers are approximately \$100,000 per year and do not constitute a material component of our business.

BioZone Pharma was incorporated as a Nevada corporation on December 4, 2006 under the name International Surf Resorts Inc. Its name was changed to BioZone Pharmaceuticals, Inc. on March 1, 2011. BioZone Labs was incorporated under the laws of the State of California on June 2, 1992. Equalan was formed as a limited liability company under the laws of the State of California on January 2, 2007. Equachem was formed as a limited liability company under the laws of the State of California on March 12, 2007 under the name Chemdyn, LLC. Its name was changed to Equachem, LLC on July 25, 2007. BetaZone was formed as a Florida limited liability company on November 7, 2006. Baker Cummins Corp. was incorporated under the laws of the State of Nevada on March 31, 2011.

Our principal executive offices are located at 550 Sylvan Avenue, Suite 101, Englewood Cliffs, NJ 07632. Our telephone number is (201) 608-5101. BioZone Labs’ principal office is located at 580 Garcia Avenue, Pittsburg, California 94565. Its telephone number is (945) 723-1000.

We manufacture products to customer specifications. The following is a list of products that we manufacture:

**OTC Products.** Hair conditioners and shampoos for treatment of eczema and psoriasis; external analgesics; skin protectants; anti-fungal products; topical anesthetics; nasal sprays; wound care products; acne products; cough and cold products; anti-itch products; and skin lightening products. In general, these products are regulated by the FDA.

**Cosmetic and Beauty Products.** AHA and Beta Hydroxy products; instant firming serums; anti-aging products; body lotions; eye creams; moisture creams and lotions; facial scrubs; and facial masks. In general, these products are not regulated by the FDA.

**Dietary Supplements.** Vitamins, minerals and herbal remedies. In general, these products are not regulated by the FDA.

## **Other Business Activities – Proprietary Product Sales**

BioZone Labs manufactures two proprietary brands of skin care products, Glyderm® and Baker Cummins®, which are sold by Equalan and Baker Cummins, respectively, to United States national wholesalers, ecommerce retailers such as Drugstore.com and Skinstore.com, physicians, who use and resell our products in their physician practices and consumers who purchase our products over the internet.

We acquired the Glyderm® line of anti-aging products from Valeant Pharmaceuticals Inc. in 2007. These products, which include glycolic acid peels and moisturizers, have been used by dermatologists for over 20 years in office procedures to treat acne, skin discolorations, removal of fine lines and wrinkles and skin resurfacing. The Glyderm® brand consists of the following products:

<b>Product Name</b>	<b>Indication or Target Market</b>
Glycolic Acid Peels – 20% to 70%	Health care practitioners for in office use to improve the texture and tone of the skin and clean out pores and help even out pigmentation and give the face a fresher appearance.
Glyderm Gentle Cleanser (0.2%)	pH balanced, soap-free, non-irritating formula, which may be used on sensitive skin.
Exfoliating Cream Series (5%)	Patients beginning the Glyderm program to help to minimize the appearance of pigmentation irregularities, maintain the results of the six-week office facial program and soften fine lines
Exfoliating Cream Plus Series (10%)	Patients who have successfully used the Exfoliating Cream Series (5%)
Exfoliating Cream Plus Series with Glycolic Acid (12%) and Salicylic Acid	Patients with dry skin who have successfully used the Glyderm Cream Plus (10%)
Exfoliate Lotion Series (5%)	Patients with normal skin to help to minimize the appearance of pigmentation irregularities, maintain the results of the six-week office facial program and soften fine lines
Exfoliate Lotion Plus (10%)	Patients who have successfully used the Exfoliate Lotion Series (5%)
Exfoliate Lotion Lite Series (5%)	Patients with normal to oily skin to help to minimize the appearance of pigmentation irregularities, maintain the results of the six-week office facial program and soften fine lines.
Exfoliate Lotion Lite Plus (10%)	Patients who have successfully used the Exfoliate Lotion Lite Series (5%)
Exfoliate Solution Series, Solution (5%)	Patients with oily, non-sensitive skin to help to minimize the appearance of pigmentation irregularities, maintain the results of the six-week office facial program and soften fine lines
Exfoliate Solution Plus (10%)	Patients who have successfully used the Exfoliate Solution Series, Solution (5%)
Exfoliate Solution Plus 12% – Combination of Glycolic and Salicylic acids	Patients who have successfully used the Exfoliate Solution Plus (10%)
Hydrotone Moisturizers (Without Glycolic Acid)	Patients with dry or mature skin to alleviate the appearance of dryness associated with exfoliation
Hydrotone Lite	Patients with normal to oily skin
Hydrotone Max	Patients with extremely dry or mature skin
Simply Sunscreen SPF 30	Paba free, UVA and UVB protection sunscreen for patients of all ages and skin types to help prevent sunburn
Glyderm Gentle Eye	Blend of antioxidants and vitamin K to help hydrate skin around the eyes and reduce the appearance of dark under-eye circles
All Climates Body Lotion (10%)	Fast-absorbing Glycolic 10% lotion for patients with all skin types for use in all climates and all seasons to alleviate the appearance of dryness
Gly Mist (0.1%)	Mineral water spray that contains Glycolic acid for patients with all skin types
Gly Masque (3%)	Combination of Glycolic esters and natural rare earth for patients with all skin types to make the skin feel invigorated and smooth
Intense C Serum PM – 7.5% L-Ascorbic Acid	Form of vitamin C suitable for topical application to provide antioxidant protection, defend against damaging UVA and UVB rays, and to contribute to collagen synthesis for patients with aging and mature skin types

We acquired the Baker Cummins line of proprietary scalp and skin care products from Aero Pharmaceuticals in May 2011. These products, which include lotions and shampoos, have been recommended by dermatologists for over 20 years to treat commonly seen skin and scalp conditions. The Baker Cummins® brand consists of the following products:

<b>Product Name</b>	<b>Indication or Target Market</b>
P&S Liquid	Treatment for symptoms of psoriasis and seborrhea dermatitis by helping to loosen and remove dried skin from the scalp.
P&S Shampoo	Specially formulated shampoo designed to remove residual P&S Liquid from the hair; contains salicylic acid to control recurrent flaking and scaling of the scalp associated with seborrheic dermatitis and psoriasis
Ultramide 25 Lotion and Ultra Mide-D	Skin lotions that soften and moisturize dry, rough, cracked and calloused skin. Ultramide 25 contains a stable 25% urea formulation
X-Seb T Pearl Shampoo and X-Seb T Plus Shampoo	Therapeutic tar shampoos that relieve itching, irritation, redness, flaking and scaling associated with dandruff, seborrheic dermatitis and psoriasis of the scalp.
Acquaderm Cream	Hypoallergenic, non-comedogenic and non-greasy concentrated facial formula that provides maximum moisturization of the skin

We employ two professionals in Pittsburgh, CA, and two professionals in Miami, Florida, who market and process orders for Glyderm® and Baker Cummins products, respectively. We have no material major customers for these lines of products. Total Glyderm® and Baker Cummins product sales for the year ended December 31, 2011 were approximately \$914,000.

## **Other Business Activities – Raw Material Sales and Technology Licensing**

Equachem sells raw materials containing our proprietary delivery agents that we refer to as QuSomes® to United States manufacturers of OTC drugs and cosmetics. Also, it licenses the right to use QuSomes® to certain OTC manufacturers and to BetaZone. Total Equachem sales and royalty revenue for the year ended December 31, 2011 was approximately \$147,000.

Effective February 24, 2012, the Company and OPKO Pharmaceuticals, LLC (“OPKO”) entered into a Limited License Agreement pursuant to which OPKO acquired (i) an exclusive license to the Company’s QuoSomes and EquaSomes DDT for use in ophthalmological indications and (ii) a non-exclusive license to such technology for all other indications. Also, effective February 24, 2012, the Company and OPKO entered into a Distribution Agreement pursuant to which the Company appointed OPKO as its exclusive distributor of any drug product containing propofol as an active ingredient in combination with a compound developed by the Company based on its EquaSomes DDT technology.

### **Research and Development**

In the mid-1990s, we licensed a proprietary, patented, phospho lipid delivery technology for use in our contract manufacturing business. Subsequently we modified the lipid to enhance final product stability, ingredient penetration, ease of manufacture process, and reduction in manufacturing and raw material costs. We obtained three U.S. patents covering the composition of matter of the enhanced lipid and method of manufacturing the resulting lipid vesicle. We modified the lipid through removal of phosphate and PEGylation, which is the process of covalent attachment of polyethylene glycol polymer chains to another molecule, normally a drug or therapeutic protein.

We refer to the pegylated lipid (i.e., the lipid modified with the PEGylation process described above) used in dermatological products as QuSomes. Our Glyderm Specialty Product, Intense C Serum PM – 7.5% L-Ascorbic Acid, is formulated with QuSomes. We refer to the pegylated lipid used in liquid oral OTC products as LiquaVail; and the pegylated lipid used in gelatin capsules as HyperSorb.

Recently, we developed a pegylated lipid, which we refer to as EquaSomes, for use in combination with drugs administered by injection or infusion. In March 2011, we established a research and small scale lipid manufacturing facility, located in Princeton, New Jersey, to advance our efforts to formulate certain generic drug products with a combination of an active pharmaceutical ingredient and EquaSomes. Currently we are developing a novel formulation of propofol, a commonly used sedative. We have yet to perform any human clinical studies with respect to this product candidate. Total research and development costs for the fiscal years ended December 31, 2011 and 2010 were \$399,624 and \$240,873, respectively.

### **Intellectual Property**

The following table lists all patents and patent applications related owned or controlled by the Company or any of its wholly owned subsidiaries. All of our granted patents expire 20 years from the filing date or effective date indicated in the table unless otherwise noted.

<b>Patent Title</b>	<b>Patent or Application Number</b>	<b>Filing or Effective Date</b>
Delivery of biologically active material in a liposomal formulation for administration into the mouth	5891465	April, 1999
Liposomal delivery by iontophoresis	6048545	April, 2000
Compounds and methods for inhibition of phospholipase A2 and cyclooxygenase-2	6495596	December, 2002
Self-forming, thermodynamically stable liposomes and their applications	6610322	August, 2003
Oral Liposomal Delivery System	6776924	April, 2004
Self-forming, thermodynamically stable liposomes and their applications	6958160	October, 2005
Compounds and methods for inhibition of phospholipase A2 and cyclooxygenase-2	6998421	February, 2006
Self-forming, thermodynamically stable liposomes and their applications	7150883	December, 2006
Self-forming, thermodynamically stable liposomes and their applications	7718190	May, 2010
Self-forming, thermodynamically stable liposomes and their applications - Japan	4497765	April, 2010
<i>X-conazoles plus QuSomes</i>		
EQUA-001 (regular application) "Enhanced Delivery of Antifungal Agents"	12/006,820	January, 2008
EQUA-001 PCT, "Enhanced Delivery of Antifungal Agents"	PCT/US2009/000003	January, 2009
EQUA-001 JP	PNLG	
EQUA-001 EP, KEMP (N.111618 JHS/eg)	9701160.5	January, 2009
EQUA-003 (P), "Enhanced Delivery of Antifungal Agents"	61/128,011	May, 2008
EQUA-012 (R)	12/454,387	May, 2009
<i>Pure PEG-Lipid Conjugates</i>		

EQUA-013	61/217,627	June, 2009
EQUA-017P	61/284,065	December, 2009
EQUA-024R	12/802,197	June, 2010
EQUA-024 PCT	PCT/US2010/001590	June, 2010
<i>Cyclosporin formulation</i>		
EQUA-016P	61/273,656	August, 2009
EQUA-025R	12/802,200	June, 2010
EQUA-025 PCT	PCT/US2010/001589	June, 2010
<i>Rapamycin</i>		
EQUA-018P	61/276,953	September, 2009
EQUA-027R - "Method of treatment with Rapamycin"	12/924,038	September, 2010
EQUA-027 PCT - "Pharmaceutical compositions of Rapamycin"	PCT/US2010/002547	September, 2010

## **Customers and Marketing**

BioZone Labs sells products to more than fifty customers through two sales professionals who market development, formulation and manufacturing services to potential customers. During the year ended December 31, 2011, four customers accounted for approximately 27%, 9%, 7% and 7% of the Company's sales. Currently, our two largest customers are Matrix Initiatives and Savvier LLP. If any of these four customers discontinues or substantially reduces its purchases from us, it may have a material adverse effect on our business and financial condition. We believe that we have good relationships with our customers.

We have agreements with our contract manufacturing customers, which provide that we will be the exclusive manufacturer of the products described in the agreement for a specified term. Typically, the agreements have a three year term. Our agreements do not require customers to purchase any specific volumes of our products.

## **Manufacturing**

The primary raw materials used in making products for our contract manufacturing customers either are supplied by our customers or are readily available in large quantities from multiple sources. Similarly, the primary raw materials used in making our proprietary brand products are readily available in large quantities from multiple sources. We believe that our manufacturing facilities are cGMP compliant.

## **Growth Strategy**

Our growth strategy for our contract manufacturing business is to increase sales by establishing a dedicated sales team with industry experience who will leverage our expertise in product development and formulation to attract new contract manufacturing customers. Our growth strategy for our proprietary brand business is to hire dedicated salespeople who will introduce our proprietary brand products to regional and national wholesalers, retailers and physicians for resale in their offices.

## **Competition**

The market for contract manufacturing services is highly competitive and price sensitive and gross margins are low. Our direct competition consists of numerous contract manufacturers, such as Perrigo Company ( Nasdaq : PRGO), many of which have greater financial and other resources than we do. If one or more other OTC contract manufacturers significantly reduce their prices in an effort to gain market share, our gross revenue, profitability or market position could be adversely affected.

## **Government Regulation**

The manufacturing, processing, formulation, packaging, labeling, testing, storing, distributing, advertising and sale of our products are subject to regulation by one or more U.S. agencies, including the U.S. Food and Drug Administration ("FDA"), the Consumer Product Safety Commission ("CPSC"), Federal Trade Commission ("FTC"), as well as several foreign, state and local agencies in localities in which our products are sold. In addition, we manufacture and market certain of our products in accordance with standards set by organizations, such as the United States Pharmacopeial Convention, Inc. ("USP"). We believe that our policies, operations and products comply in all material respects with existing regulations.

### *U.S. Food and Drug Administration*

The FDA has jurisdiction over our OTC drug products and dietary supplements. The FDA's jurisdiction extends to the manufacturing, testing, labeling, packaging, storage and distribution of these products.

In general, OTC medicines are marketed under regulations referred to as "OTC monographs", which have been established through the FDA's OTC Review procedures. Under the OTC monograph system, selected OTC drugs are generally recognized as safe and effective and do not require the submission and approval of a New Drug Application ("NDA") or an Abbreviated New Drug Application ("ANDA") prior to marketing. The OTC monograph specifies allowable combinations of ingredients and dosage levels, permitted indications, and required warnings and precautions. Drug products marketed under the OTC monograph system must conform to specific quality and labeling requirements.

The OTC monograph regulations related to the OTC products that we manufacture may change from time to time, requiring formulation, packaging or labeling changes for certain products. We cannot predict whether new legislation regulating our activities will be enacted or what effect any legislation would have on our business.

All facilities where OTC drugs are manufactured, tested, packaged, stored or distributed must comply with FDA cGMPs. All of our OTC drug products are manufactured, tested, packaged, stored and distributed according to cGMP regulations. The FDA performs periodic audits to ensure that our facilities remain in compliance with appropriate regulations. The failure of our facility to be in compliance may lead to regulatory action against us that could result in the suspension of production or distribution of our products, product seizures, loss of certain licenses or other governmental penalties, and could have a material adverse effect on our financial condition or operating results. In addition, new legislation regulating our activities could be enacted with a negative impact on our business.

In January and November 2011, the FDA performed two separate GMP surveillance inspections of BioZone Labs' manufacturing facility and warehouse located at 580 Garcia Avenue, Pittsburg, CA. to audit our compliance against 21CFR Part 210 and Part 211, Good Manufacturing Practices with respect to our OTC drug product manufacturing procedures. Both inspections were routine GMP surveillance audits and were not triggered by any specific event, nor were they related to a specific product. At the conclusion of each audit, the FDA inspectors issued Form 483 Notice of Observations. The FDA's observations related to maintenance of data derived from tests necessary to assure compliance with established specifications, deviations from test procedures, standards for rejecting drug products failing to meet established specifications, maintenance of electronic records, accessibility of written records, preparation of GLP documentation concurrent with performance, process validation and warehouse controls. We provided adequate and timely responses to the FDA findings and provided commitments and timelines for the remediation of the conditions cited by the FDA. The FDA classified the inspections as VAI, Voluntary Action Indicated, and no Warning Letters were issued, which demonstrates the adequacy of our responses.

#### *Consumer Product Safety Commission*

The packaging of certain our products is subject to regulation under the Poison Prevention Packaging Act ("PPPA"), pursuant to which the CPSC has authority to require dietary supplements and pharmaceuticals to be packaged in child-resistant packaging to help reduce the incidence of accidental poisonings. The CPSC has published regulations requiring iron-containing dietary supplements and numerous pharmaceuticals to have child resistant packaging, and has established rules for testing the effectiveness of child-resistant packaging and for ensuring senior adult effectiveness.

The Consumer Product Safety Improvement Act of 2008 amended the Consumer Product Safety Act (CPSA) to require that the manufacturer of any product that is subject to any CPSC rule, ban, standard or regulation certify that the product complies with such requirements based on a reasonable testing program. This certification applies to pharmaceuticals and dietary supplements that require child-resistant packaging under the PPPA. We rely on the manufacturer of our packaging supplies for compliance with such requirements.

#### *Federal Trade Commission*

The FTC exercises primary jurisdiction over the advertising and other promotional practices of marketers of OTC pharmaceuticals and dietary supplements and often works with the FDA regarding these practices. The FTC considers whether a product's claims are substantiated, truthful and not misleading. The FTC is also responsible for reviewing mergers between and acquisitions of pharmaceutical companies exceeding specified thresholds and investigating certain business practices relevant to the healthcare industry. The FTC could challenge these business practices in administrative or judicial proceedings. Although we do not market or advertise any OTC pharmaceuticals and dietary supplements, we are responsible for the accuracy of the claims made on the labels of products that we manufacture.

#### *State Regulation*

We are subject to state laws that regulate foods and drugs under laws that generally parallel federal statutes. Also, we are subject to state consumer health and safety regulations. Failure to comply with these laws and regulations could have a significant negative impact on our business.

#### *United States Pharmacopeial Convention*

The USP is a non-governmental, standard-setting organization. By reference, the Federal Food, Drug and Cosmetic Act incorporates the USP quality and testing standards and monographs as the standards that must be met for the listed drugs, unless compliance with those standards is specifically disclaimed on the product's labeling. USP standards exist for most Rx and OTC pharmaceuticals and many nutritional supplements. The FDA typically requires USP compliance as part of cGMP compliance.

#### **Product Liability**

We may be subject to product liability claims by consumers of our products. We maintain product liability insurance policies which provide coverage in the amount \$5 million per occurrence and \$5 million in the aggregate. A product liability claim, if successful and in excess of our insurance coverage, could have a material adverse effect on our financial condition.

#### **Seasonality**

Many of our products include cough/cold remedies, which are often sold in the winter months. Accordingly, our business is cyclical. Approximately two thirds of our revenue is generated in the second half of the calendar year.

#### **Employees**

We currently employ 82 full time and 99 seasonal employees at our Pittsburg, California facilities, five employees in Princeton, New Jersey, two employees in Englewood Cliffs, New Jersey and two employees in Miami, Florida. These employees perform various, manufacturing, sales, marketing, research and development, and administration functions. We believe that our relations with our employees are good.

#### **Item 1A. Risk Factors.**

Investing in our common stock involves a high degree of risk. Prospective investors should carefully consider the risks described below and other information contained in this annual report, including our financial statements and related notes before purchasing shares of our common stock. There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. If any of these risks actually occurs, our business, financial condition or results of operations may be materially adversely affected. In that case, the trading price of our common stock could decline and investors in our common stock could lose all or part of their investment.

**Risks related to our Company**

**We have not had profitable operations in recent periods, and our financial losses may continue in the future.**

We have recognized net losses for the years ended December 31, 2011 and 2010, and expect to incur a net loss for the year ended December 31, 2012. We are reviewing our manufacturing cost structure to identify inefficiencies and opportunities for reductions and our sales programs to identify opportunities for increasing sales volume. Although we anticipate that these efforts will reduce or eliminate ongoing losses from our manufacturing business and allow us to continue manufacturing operations for the foreseeable future, there can be no assurance that our cost reduction and increased sales efforts will prove successful.

## **We have negative working capital.**

As of December 31, 2011, we had negative working capital of \$4,373,734, which may impact our ability to raise needed capital. Our failure to raise capital when needed would adversely affect our growth opportunities and investment in capital expenditures.

## **Our independent auditor has issued an audit opinion which includes a statement describing a substantial doubt whether we will continue as a going concern, which may have a detrimental effect on our ability to obtain additional financing.**

The continuation of the Company as a going concern is dependent upon, among other things, the attainment of profitable operations and the ability of the Company to obtain necessary equity or debt financing. These factors, among others, raise substantial doubt regarding the Company's ability to continue as a going concern. Accordingly, the audit report prepared by our independent registered public accounting firm relating to the consolidated financial statements for the year ended December 31, 2011 and December 31, 2010 includes an explanatory paragraph expressing substantial doubt about its ability to continue as a going concern. Our auditor's going concern opinion may have a detrimental effect on our ability to obtain additional funding.

## **Our business will require additional capital for continued growth, and our growth may be slowed if we do not have sufficient capital.**

The continued growth and operation of our business will require additional funding for working capital. We may be unable to secure such funding when needed in adequate amounts or on acceptable terms, if at all. To execute our business strategy, we may issue additional equity securities in public or private offerings, potentially at a price lower than the market price at the time of such issuance. The issuances of additional securities in public and private offerings will dilute our current investors' interest in the Company. Similarly, we may seek debt financing and may be forced to incur significant interest expense. The issuance of debt securities may provide such holders with rights superior to existing shareholders. If we cannot secure sufficient funding, we will be forced to forego strategic opportunities or delay, scale back or eliminate operations, acquisitions, and other investments.

Our ability to obtain needed financing may be impaired by such factors as the condition of the economy and capital markets, both generally and specifically in our industry, and the fact that we are not profitable, which could impact the availability or cost of future financings. If the amount of capital we are able to raise from financing activities, together with our revenues from operations, is not sufficient to satisfy our capital needs, even to the extent that we reduce our operations accordingly, we may be required to cease operations. As of the date of this report, we have not approached any new sources for additional funding and have not entered into negotiations for a transaction, other than those transactions that have already been disclosed in our filings with the SEC.

## **Risks related to our industry**

### **We operate in a highly regulated industry. An inability to meet current or future regulatory requirements in the United States or foreign jurisdictions could have a material adverse effect on our business, financial position and operating results.**

All facilities where Rx and OTC drugs are manufactured, tested, packaged, stored or distributed must comply with the FDA's Current Good Manufacturing Processes ("cGMPs"). All of our drug products are manufactured, tested, packaged, stored and distributed according to cGMP regulations. The FDA performs periodic audits to ensure that our facilities remain in compliance with all appropriate regulations. Typically, after the FDA completes its inspection, it may or may not issue the Company a report on Form 483, Notice of Observations., containing the FDA's observations of possible violations of cGMP. These violations can range from minor to severe in nature. The degree of severity of the violation is generally determined by the time necessary to remediate the cGMP violation, and any adverse consequences for the consumer of our drug products. If the deficiency observations are determined to be severe, the FDA may elect to issue a Warning Letter to us. FDA guidelines specify that a warning letter be issued only for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in further enforcement action. In addition to making its concerns public, the FDA could impose sanctions including, among others, fines, product recalls, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, injunctions and civil or criminal prosecution. These enforcement actions, if imposed, could have a material adverse effect on our operating results and financial condition. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. In January and November 2011, the FDA performed two separate GMP surveillance inspections of BioZone Labs to audit our compliance against 21CFR Part 210 and Part 211, Good Manufacturing Practices. Both inspections were routine GMP surveillance audits and were not triggered by any specific event, nor were they related to a specific product. At the conclusion of each audit, the FDA inspectors issued Form 483 Notice of Observations. We provided adequate and timely responses to the FDA findings and provided commitments and timelines for the remediation of the conditions cited by the FDA. The FDA classified the inspections as VAI, Voluntary Action Indicated, and no Warning Letters were issued, which demonstrates the adequacy of our responses. As of the date hereof, we have not received any additional correspondence from the FDA regarding these two inspections. We believe that the remedial actions we are taking adequately respond to the FDA's observations on Form 483. However, the FDA may conclude that our actions are insufficient to meet regulatory standards. If compliance is deemed deficient in any significant way, it could have a material adverse effect on our business. See "Government Regulation" in Item 1 for further discussion concerning Form 483 received by the Company.

In addition to the FDA, several U.S. agencies regulate the manufacturing, processing, formulation, packaging, labeling, testing, storing, distribution, advertising and sale of our products. Various state and local agencies also regulate these activities. Should any of our third party pharmaceutical ingredient suppliers fail to adequately conform or comply with manufacturing, quality and testing guidelines and regulations, we could experience a significant adverse impact on our operating results.

## **Significant increases in the cost of raw materials used in our contract manufacturing business could adversely impact our profit margins and operating results.**

Affordable high quality raw materials and packaging components are essential to our business due to the nature of the products we

manufacture. Our contract manufacturing customers either supply us with the raw materials and packaging components necessary to manufacture their finished products or reimburse us for the cost of such materials and components. Moreover, the raw materials and packaging components that we use are generally available from multiple suppliers and we have not experienced any problems with contaminated raw materials that would impact our business. However, a rapid increase in cost of raw materials from various factors, such as inflationary forces or scarcity, could have a material impact on our financial results if we are unable to pass on these increased costs to our customers.

**If we fail to obtain, apply for, adequately prosecute to issuance, maintain, protect or enforce patents for our inventions and products, the value of our intellectual property rights and our ability to license, make, use or sell our products would materially diminish or could be eliminated entirely.**

Our competitive position and future revenues, especially with regard to our strategy to leverage the BioZone Technology to increase sales, will depend in part on our ability to obtain and maintain patent protection for our inventions and products and for methods, processes and other technologies, as well as our ability to preserve our trade secrets, prevent third parties from infringing on our proprietary rights or invalidating our patents and operate without infringing the proprietary rights of third parties. The risks include the following:

- Some of our issued patents or any patents that are issued to us in the future may be determined to be invalid and/or unenforceable, or may offer inadequate protection against competitive products;
- If we have to defend the validity of our patents or any future patents or protect against third party infringements, the costs of such defense are likely to be substantial and we may not achieve a successful outcome;
- Others may obtain patents claiming aspects similar to those covered by our patents and patent applications, which could enable them to make and sell products similar to ours; and
- We may be estopped from claiming that one or more of our patents is infringed due to amendments to the claims and/or specification, or as a result of arguments that were made during prosecution of such patents in the United States Patent and Trademark Office, or by virtue of certain language in the patent application. The estoppel may result in claim limitation and/or surrender of certain subject matter to the public domain or the ability of competitors to design around our claims and/or avoid infringement of our patents. If our patents or those patents for which we have license rights become involved in litigation, a court could revoke the patents or limit the scope of coverage to which they are entitled.

If we fail to obtain and maintain adequate patent protection and trade secret protection for our products, proprietary technologies and their uses, we could lose any competitive advantage and the competition we face could increase, thereby reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

**A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly and an unfavorable outcome could harm our business.**

There is significant litigation in the biotechnology field regarding patents and other intellectual property rights. We may be exposed to future litigation by third parties based on claims that our products, technologies or activities infringe the intellectual property rights of others. Although we try to avoid infringement, and as of the date hereof, there are no claims against us alleging infringement, there is the risk that we will use a patented technology owned or licensed by another person or entity and/or be sued for infringement of a patent owned by a third party. Under current United States law, patent applications are confidential for 18 months following their priority filing date and may remain confidential beyond 18 months if no foreign counterparts are applied for in jurisdictions that publish patent applications. There are many patents relating to the use of lipids and liposomes. If our products or methods are found to infringe any patents, we may have to pay significant damages and royalties to the patent holder or be prevented from making, using, selling, offering for sale or importing such products or from practicing methods that employ such products.

In addition, we may need to resort to litigation to enforce our patents issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. Such litigation could be expensive and there is no assurance that we would be successful. From time to time, we may hire scientific personnel formerly employed by other companies involved in one or more fields similar to the fields in which we are working. Either these individuals or we may be subject to allegations of trade secret misappropriation or similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. As a result, we could be prevented from commercializing current or future products or methods.

**Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property.**

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors and contractors. We enter into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. These agreements generally require that the receiving party keep confidential and not disclose to third parties all confidential information developed by the receiving party or made known to the receiving party by us during the course of the receiving party's relationship with us. These agreements also generally provide that inventions conceived by the receiving party in the course of rendering services to us will be our exclusive property. However, these agreements may be breached and may not effectively assign intellectual property rights to us. Our trade secrets also could be independently discovered by competitors, in which case we would not be able to prevent use of such trade secrets by our competitors. The enforcement of a claim alleging that a party illegally obtained and was using our trade secrets could be difficult, expensive and time consuming and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. The failure to obtain or maintain meaningful trade secret protection could adversely affect our competitive position.

## **We face significant competition.**

The contract manufacturing business is highly competitive and price sensitive. We face competition from multiple competitors, some of whom are larger and more financially secure than we. They may reduce prices to an unacceptably low level for us in order to increase sales. Therefore, we can make no assurance that we will grow our contract manufacturing business or maintain our current level of sales in the future.

Our proprietary skin care products compete against other similar products marketed by companies much larger than we and who spend much more than us on consumer advertising. The skin care product business is highly promotion sensitive and we have a limited advertising budget. Therefore, we can make no assurance that we will grow sales of our proprietary skin care brands or maintain our current level of sales in the future.

## **Risks related to management**

### **We rely on key executive officers and their knowledge of our business and technical expertise would be difficult to replace.**

We are highly dependent on Elliot Maza, JD, CPA, our Chief Executive and Chief Financial Officer, Dr. Brian Keller, our President and Chief Scientific Officer, and Christian Oertle, our Chief Operating Officer. We do not have “key person” life insurance. The loss of Mr. Maza, Dr. Keller or Mr. Oertle may have an adverse effect on our business. We have entered into three year employment contracts with Dr. Keller and Mr. Oertle. Each of the employment agreements may be terminated by the Company at will, subject to an obligation to pay severance for six months at the then applicable monthly base salary.

### **Elliot Maza, our Chief Executive Officer, Chief Financial Officer and Secretary, devotes a portion of his business time to another enterprise.**

Elliot Maza, our Chief Executive Officer, Chief Financial Officer and Secretary, does not work for us exclusively as he is also the Chief Financial Officer of Intellect Neurosciences, Inc., a biotechnology company focused on the development of therapeutics for Alzheimer’s disease. We do not consider Intellect Neurosciences, Inc. to be a competitor of the Company. Mr. Maza devotes approximately 30 hours per week to Company matters, compared to approximately 10 hours per week Mr. Maza devotes to Intellect Neurosciences, Inc. matters. It is possible that a conflict of interest may arise with respect to Mr. Maza’s other employment.

### **Our officers and directors hold a substantial number of shares of our common stock.**

Our officers and, directors and their affiliates own or control an aggregate of 10,200,000 shares of the Company’s common stock, which represents approximately 18.1% of our issued and outstanding common stock as of April 16, 2012. Therefore, our officers and directors could exert substantial influence over election of our directors and our operations. Moreover, authorization to modify our Articles of Incorporation, as amended, requires only majority stockholder consent. This concentration of ownership could also have the effect of delaying or preventing a change in control. Additionally, potential conflicts of interest may arise between our officers and directors and our shareholders and our officers and directors may vote their shares in a way that our other shareholders do not approve.

### **Our obligations to indemnify our directors and officers may pose substantial risks to our financial condition.**

We have obtained directors’ and officers’ liability insurance insuring our directors and officers against liability for acts or omissions in their capacities as directors or officers, subject to certain exclusions. Such insurance also insures us against losses which we may incur in indemnifying our officers and directors. In addition, we may enter into indemnification agreements with key officers and directors and such persons shall also have indemnification rights under applicable laws, and the Company’s Articles of Incorporation and Bylaws. Our obligations to indemnify our directors and officers may pose substantial risks to our financial condition, as we may not be able to maintain our insurance or, even if we are able to maintain our insurance, claims in excess of our insurance coverage could materially deplete our assets.

## **Risks related to our common stock**

### **Shares of our stock suffer from low trading volume and wide fluctuations in market price.**

Our common stock is currently quoted on the Over the Counter Bulletin Board trading system under the symbol BZNE. Currently, an investment in our common stock is illiquid and subject to significant market volatility. This illiquidity and volatility may be caused by a variety of factors including low trading volume and market conditions.

Stockholders may experience wide fluctuations in the market price of our securities. These fluctuations may prevent a stockholder from obtaining a market price equal to the purchase price such stockholder paid when the stockholder attempts to sell our securities in the open market. In these situations, the stockholder may be required either to sell our securities at a loss or hold our securities for a longer period of time than planned.

Also, the inactive market for our common stock may impair our ability to raise capital, acquire other companies in exchange for stock, or recruit and retain managers with equity-based incentive plans. There has been limited trading in our common stock and there can be no assurance that an active trading market in our common stock will either develop or be maintained. In addition, we believe that factors such as quarterly fluctuations in our financial results and changes in the overall economy or the condition of the financial markets could cause the price of our common stock to fluctuate substantially. These fluctuations may cause short sellers to periodically enter the market in the belief that we will have poor results in the future. We cannot predict the actions of market participants and can offer no assurances that the market for our common stock will be stable or appreciate over time.

In addition, the value of our common stock could be affected by changes in the market valuations of other similarly situated companies serving similar markets; announcements by us or our competitors of significant acquisitions, strategic partnerships, collaborations, joint ventures or capital commitments; adoption of new accounting standards affecting our industry; additions or departures of key personnel; introduction of new products or services by us or our competitors; actual or expected sales of our common stock or other securities in the open market; conditions or trends in the market in which we operate; and other events or factors, many of which are beyond our control.

**We cannot assure you that our common stock will become listed on NYSE Amex Equities, Nasdaq or any other securities exchange.**

We plan to seek listing of our common stock on NYSE Amex Equities or Nasdaq within the next three years. However, we do not currently meet the initial listing standards of those exchanges and there are no assurances that we will be able to meet the initial listing standards of either of those or any other stock exchange, or that we will be able to maintain a listing of our common stock on either of those or any other stock exchange. Currently, we fall below the bid price requirement of \$4.00 per share for Nasdaq and do not currently meet the corporate governance standards of either Nasdaq or NYSE Amex Equities. Until our common stock is listed on NYSE Amex Equities or Nasdaq or another stock exchange, we expect that our common stock will continue to trade on the Over-The-Counter Bulletin Board, where an investor may find it difficult to dispose of our shares of common stock.

**We will incur significant costs as a result of being an operating public company.**

As a public operating company, we will incur significant legal, accounting and other expenses not incurred by a private company. If our stock becomes listed on Nasdaq or another major exchange or if our total assets exceed \$10 million at the end of any fiscal year, we will also incur additional compliance expenses. It may be time consuming, difficult and costly for us to develop and implement the additional internal controls, processes and reporting procedures required by the Sarbanes-Oxley Act of 2002, SEC proxy rules, other government regulations affecting public companies and/or stock exchange compliance requirements. As we currently do not have a large financial reporting, internal auditing and other finance staff, we may need to hire additional financial reporting, internal auditing and other finance staff in order to develop and implement appropriate additional internal controls, processes and reporting procedures. We anticipate incurring approximately \$100,000 in legal costs and \$100,000 in accounting costs over the next 12 months as a result of our public company status.

**Our common stock is subject to the “Penny Stock” rules of the SEC, which makes transactions in our stock cumbersome and may reduce the value of an investment in our stock.**

Our common stock is considered a “Penny Stock”. The Securities and Exchange Commission has adopted Rule 15g-9 which generally defines "penny stock" to be any equity security that has a market price (as defined) less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exceptions. Our securities are covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and "accredited investors". The term "accredited investor" refers generally to institutions with assets in excess of \$5,000,000 or individuals with a net worth in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 jointly with their spouse. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from these rules; the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny stock rules discourage investor interest in and limit the marketability of our common stock. The Financial Industry Regulatory Authority, or FINRA, has adopted sales practice requirements which may also limit a stockholder's ability to buy and sell our stock. In addition to the "penny stock" rules described above, FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit investors' ability to buy and sell our stock and have an adverse effect on the market for our shares.

**We have never paid nor do we expect in the near future to pay dividends.**

We have never paid cash dividends on our capital stock and do not anticipate paying any cash dividends on our common stock for the foreseeable future. Investors should not rely on an investment in our Company if they require income generated from dividends paid on our capital stock. Any income derived from our common stock would only come from rise in the market price of our common stock, which is uncertain and unpredictable.

**We and our security holders are not subject to some reporting requirements applicable to most public companies; therefore, investors may have less information on which to base an investment decision.**

We do not have a class of securities registered under Section 12(b) or 12(g) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Therefore, we do not prepare proxy or information statements in accordance with Section 14(a) of the Exchange Act with respect to matters submitted to the vote of our security holders, including, but not limited to, an increase in our authorized capital stock or the adoption of stock option plans. Our officers, directors and beneficial owners of more than 10% of our common stock are not required to file statements of beneficial ownership on SEC Forms 3, 4 and 5 pursuant to Section 16 of the Exchange Act, which such forms would disclose the reporting person's initial ownership interest in our Company and would be subsequently updated to disclose any additional transactions. Beneficial owners of more than 5% of our outstanding common stock are not required to file reports on SEC Schedules 13D or 13G. Therefore, investors in our securities will not have any such information available in making an investment decision.



### **We lack proper internal controls and procedures.**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive, as appropriate, to allow timely decisions regarding required disclosure based on the definition of "disclosure controls and procedures" in Rule 13a-15(e). In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management has identified certain material weaknesses relating to our internal controls and procedures. The reason for the ineffectiveness of our disclosure controls and procedures was the result of the lack of segregation of duties and responsibilities with respect to our cash control over the disbursements related thereto. The lack of segregation of duties resulted from our limited accounting staff.

### **We may fail to qualify for continued listing on the OTC Bulletin Board, which could make it more difficult for investors to sell their shares.**

Our common stock is quoted on the Over the Counter Bulletin Board ("OTCBB"). There can be no assurance that quotation of our common stock will be sustained. In the event that our common stock fails to qualify for continued quotation, our common stock could thereafter only be quoted on the "pink sheets." Under such circumstances, shareholders may find it more difficult to dispose of, or to obtain accurate quotations, for our common stock, and our common stock would become substantially less attractive to certain purchasers such as financial institutions, hedge funds and other similar investors.

### **Investor relations activities, nominal "float" and supply and demand factors may affect the price of our stock.**

The Company expects to utilize various techniques such as non-deal road shows and investor relations campaigns in order to create investor awareness for the Company. These campaigns may include personal, video and telephone conferences with investors and prospective investors in which our business practices are described. The Company may provide compensation to investor relations firms and pay for newsletters, websites, mailings and email campaigns that are produced by third-parties based upon publicly-available information concerning the Company. The Company does not intend to review or approve the content of such analysts' reports or other materials based upon analysts' own research or methods. Investor relations firms should generally disclose when they are compensated for their efforts, but whether such disclosure is made or complete is not under our control. In addition, investors in the Company may, from time to time, also take steps to encourage investor awareness through similar activities that may be undertaken at the expense of the investors. Investor awareness activities may also be suspended or discontinued which may impact the trading market our common stock.

The SEC and FINRA enforce various statutes and regulations intended to prevent manipulative or deceptive devices in connection with the purchase or sale of any security and carefully scrutinize trading patterns and company news and other communications for false or misleading information, particularly in cases where the hallmarks of "pump and dump" activities may exist, such as rapid share price increases or decreases. We, and our shareholders may be subjected to enhanced regulatory scrutiny due to the small number of holders who initially will own the registered shares of our common stock publicly available for resale, and the limited trading markets in which such shares may be offered or sold which have often been associated with improper activities concerning penny-stocks, such as the OTC Bulletin Board or the OTCQB Marketplace (Pink OTC) or pink sheets. Until such time as our restricted shares are registered or available for resale under Rule 144, there will continue to be a small percentage of shares held by a small number of investors, many of whom acquired such shares in privately negotiated purchase and sale transactions, which will constitute the entire available trading market. The Supreme Court has stated that manipulative action is a term of art connoting intentional or willful conduct designed to deceive or defraud investors by controlling or artificially affecting the price of securities. Often times, manipulation is associated by regulators with forces that upset the supply and demand factors that would normally determine trading prices. Since a small percentage of the outstanding common stock of the Company will initially be available for trading, held by a small number of individuals or entities, the supply of our common stock for sale will be extremely limited for an indeterminate amount of time, which could result in higher bids, asks or sales prices than would otherwise exist. Securities regulators have often cited factors such as thinly-traded markets, small numbers of holders, and awareness campaigns as hallmarks of claims of price manipulation and other violations of law when combined with manipulative trading, such as wash sales, matched orders or other manipulative trading timed to coincide with false or touting press releases. There can be no assurance that the Company's or third-parties' activities, or the small number of potential sellers or small percentage of stock in the "float," or determinations by purchasers or holders as to when or under what circumstances or at what prices they may be willing to buy or sell stock will not artificially impact (or would be claimed by regulators to have affected) the normal supply and demand factors that determine the price of the stock.

### **Item 2. Properties.**

Our facilities are located in Pittsburg, California, Princeton, New Jersey, Miami, Florida and Englewood Cliffs, New Jersey.

BioZone Labs manufactures its products in a 20,000 s.f., cGMP facility owned by 580 Garcia Avenue, LLC, its consolidated VIE and fills and stores its products at a 60,000 sq. ft. rented facility located at 701 Willow Pass Road, Pittsburg, CA. The lease for the Willow Pass Road facility expires on April 30, 2015 and provides for annual rentals of approximately \$343,000

We lease approximately 1,500 square feet of office space at 4400 Biscayne Boulevard, Miami, Florida where we employ two sales professional for our Baker Cummins brand proprietary skin care products. The lease expires on October 31, 2012 and provides for annual rentals of approximately \$24,750. Our rent expense for our Miami facility until the lease expires is \$20,650:

In July 2011, we entered into a lease for approximately 3,869 square feet of laboratory space in Princeton, New Jersey where we conduct research and development activities related to our proprietary drug delivery technology. The lease expires on July 20, 2016. Rent expense is

\$8,065 per month.

Our corporate headquarters is located at 550 Sylvan Avenue, Englewood Cliffs, New Jersey, where we lease approximately 800 square feet of office space. The lease expires on June 30, 2012. Rent expense is approximately \$1,450 per month.

### **Item 3. Legal Proceedings.**

We are not involved in any pending legal proceeding or litigation that we believe would have a material impact upon our business or results of operations.

#### Aphena Pharma Solutions – Maryland, LLC f/k/a Celeste Contract Packaging, LLC, v. BioZone Laboratories, Inc. and BioZone Pharmaceuticals, Inc. and Daniel Fisher, District Court for the District of Maryland Northern Division; Case 1:12-cv-00852-WDQ

An action was initiated recently against BioZone Labs, BioZone Pharma and a former officer and director in the United States District Court for the District of Maryland on March 19, 2012. The plaintiff alleges breach of contract and other commercial wrongdoing in connection with a single purchase order issued during early 2010 relating to the development of certain over the counter products to treat cough and cold symptoms. The Company refutes the allegations and intends to vigorously defend against this action.

#### BioZone Laboratories, Inc. v. ComputerShare Trust Co., N.A. and Cardium Therapeutics, Inc. District Court, State of Colorado, County of Jefferson, Case No. 2012CV406

The Company commenced the above action, by filing of a Summons and Complaint, on February 2, 2012 for declaratory relief, specific performance and monetary damages against Defendants ComputerShare Trust Co., N.A. (“ComputerShare”) and Cardium Therapeutics, Inc. (“Cardium”) (collectively, the “Defendants”). This action arises from, inter alia, the failure of ComputerShare, which was acting as an escrow agent in connection with the Company’s purchase of Cardium stock, to deliver such stock to the Company as required by an Escrow Agreement entered into between the Company and Defendants. By Order, dated March 30, 2012, the Court dismissed this action on the ground that venue was improper in Colorado.

### **Item 4. Mine Safety Disclosures.**

Not Applicable.

## **PART II**

### **Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

#### **Market Information**

Our common stock has been quoted on the OTC Bulletin Board under the symbol “BZNE.OB” since March 7, 2011 and prior to that under the symbol “ISFR”. The following table sets forth the high and low prices as reported on the OTC Bulletin Board. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. Prior to May 19, 2011, there was no active market for our common stock. As of April 16, 2012, there were approximately 83 holders of record of our common stock.

<b>Period</b>	<b>High</b>	<b>Low</b>
May 19, 2011 through June 30, 2011	\$ 5.50	\$ 1.50
July 1, 2011 through September 30, 2011	\$ 4.65	\$ 1.50
October 1, 2011 through December 31, 2011	\$ 4.64	\$ 3.68

The last reported sales price of our Common stock on the OTC Bulletin Board on April 13, 2012 was \$3.52 per share.

#### **DIVIDEND POLICY**

We have not declared nor paid any cash dividend on our Common stock, and we currently intend to retain future earnings, if any, to finance the expansion of our business, and we do not expect to pay any cash dividends in the foreseeable future. The decision whether to pay cash dividends on our Common stock will be made by our board of directors, in their discretion, and will depend on our financial condition, results of operations, capital requirements and other factors that our board of directors considers significant.

#### **Securities Authorized for Issuance under Equity Compensation Plans**

We have not adopted an equity compensation plan to date.

#### **Recent Sales of Unregistered Securities**

On March 13, 2012, we sold a 10% senior convertible promissory note (the “Note”) to an accredited investor (the “Investor”) for an aggregate purchase price of \$1,000,000. The principal amount of the Note is payable in cash on such dates and in such amounts as set forth in the Note, based on the receipt of proceeds from sales to a certain vendor (the “Vendor Proceeds”). The last date of such scheduled payment shall be referred to as the “Final Maturity Date”. The Company may prepay any outstanding amounts owing under the Note, in whole or in part, at any time prior to the Final Maturity Date. The entire remaining principal amount and all accrued but unpaid or unconverted interest thereof, shall be due and payable on the earliest of (1) the Final Maturity Date, (2) the consummation of a financing by the Company resulting in net proceeds equal to or greater than 1.5 times the remaining outstanding unconverted principal amount hereunder and (3) the occurrence of an Event of Default (as defined in the Note). The Note is convertible into shares of the Company’s common stock at an initial conversion price of \$1.50 per share. All of the Company’s obligations under the Note are secured by a first priority security interest in the Vendor Proceeds. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public

offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On March 1, 2012, the Company issued 455,000 shares of its common stock to certain individuals who previously purchased shares of the Company's common stock on November 3, 2011 at a purchase price of \$1.00 per share. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On February 24, 2012, we entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with a purchaser (the "Buyer") pursuant to which we sold (i) \$1,700,000 of 10% secured convertible promissory note (the "Note") due two years from the date of issuance (the "Maturity Date") and (ii) warrants (the "Warrants") to purchase 8,500,000 shares of the Company's common stock at an exercise price of \$0.40 per share for gross proceeds to us of \$1,700,000. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On February 27, 2012, the Company issued warrants to purchase 1,000,000 shares of the Company's common stock at an exercise price of \$0.60 per share to the former holders of the March 2011 Notes described in Note 6 – Convertible Notes Payable in connection with the repayment of those notes. The transaction did not involve any underwriters, underwriting discounts or commissions of any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On February 28, 2012 and February 29, 2012, we sold an additional \$600,000 of Notes and issued Warrants to purchase an additional 3,000,000 shares of the Company's common stock to additional Buyers for gross proceeds to the Company of \$600,000.

The entire principal amount and any accrued and unpaid interest on the Notes shall be due and payable in cash on the Maturity Date. The Notes bear interest at the rate of 10% per annum. The Notes are convertible into shares of the Company's common stock at an initial conversion price of \$0.20 per share, subject to adjustment. The Company may prepay any outstanding amount due under the Notes, in whole or in part, prior to the Maturity Date. The Notes are subject to certain "Events of Defaults" which could cause all amounts due and owing thereunder to become immediately due and payable. Among other things, the Company's failure to pay any accrued but unpaid interest when due, the failure to perform any obligation under the Transaction Documents (as defined herein) or if any representation or warranty made by the Company in connection with the Transaction Documents shall prove to have been incorrect in any material respect, shall constitute an Event of Default under the Transaction Documents. The Warrant is immediately exercisable and expires ten years after the date of issuance. The Warrant has an initial exercise price of \$0.40 per share. The Warrant is exercisable in cash or, while a registration statement covering the shares of Common Stock issuable upon exercise of the Warrant, or an exemption from registration, is not available, by way of a "cashless exercise".

The Company is prohibited from effecting a conversion of the Notes or exercise of the Warrants, to the extent that as a result of such conversion or exercise, the Buyer would beneficially own more than 4.99% (subject to waiver) in the aggregate of the issued and outstanding shares of the Company's common stock, calculated immediately after giving effect to the issuance of shares of common stock upon conversion of such Note or exercise of such Warrant, as the case may be. In connection with the sale of the Notes and the Warrants, the Company and the collateral agent for the Buyers entered into a Pledge and Security Agreement (the "Security Agreement" and, collectively with the Securities Purchase Agreement, the Note and the Warrant, the "Transaction Documents") pursuant to which all of the Company's obligations under the Notes are secured by a first priority perfected security interest in all of the tangible and intangible assets of the Company, including all of its ownership interest in its subsidiaries. The Company has granted the Buyers "piggy-back" registration rights with respect to the shares of common stock underlying the Notes and the shares of common stock underlying the Warrants, for a period of twelve (12) months from the date of closing.

On January 25, 2012, we sold an aggregate of 700,000 units (the "Units") with gross proceeds to the Company of \$350,000. Each Unit was sold for a purchase price of \$0.50 per Unit and consists of: (i) one share of Common Stock and (ii) a four-year warrant to purchase fifty (50%) percent of the number of shares of Common Stock purchased at an exercise price of \$1.00 per share, subject to adjustment upon the occurrence of certain events (the "Warrant"). The Warrants may be exercised on a cashless basis after twelve (12) months from the date of closing, if there is no effective registration statement covering the shares of Common Stock issuable upon exercise of the Warrant. The Company has granted the investors "piggy-back" registration rights with respect to the shares of common stock underlying the Units and the shares of common stock underlying the Warrants, for a period of twelve (12) months from the date of closing. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On January 11, 2012, we sold an aggregate of 600,000 Units with gross proceeds to the Company of \$300,000. Each Unit was sold for a purchase price of \$0.50 per Unit and consists of: (i) one share of Common Stock and (ii) a four-year warrant to purchase fifty (50%) percent of the number of shares of Common Stock purchased at an exercise price of \$1.00 per share, subject to adjustment upon the occurrence of certain events (the "Warrant"). The Warrants may be exercised on a cashless basis after twelve (12) months from the date of closing, if there is no effective registration statement covering the shares of Common Stock issuable upon exercise of the Warrant. The Company has granted the investors "piggy-back" registration rights with respect to the shares of common stock underlying the Units and the shares of common stock underlying the Warrants, for a period of twelve (12) months from the date of closing. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On November 30, 2011, we issued 500,000 shares of common stock, par value \$0.001 per share, at a purchase price of \$0.50 per share pursuant to a subscription agreement. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On November 30, 2011, we issued 1,018,356 shares of common stock, par value \$0.001 per share, upon conversion of the principal and all of the interest due on a certain convertible promissory note issued on September 22, 2011. The Company also issued the holder a warrant to purchase 500,000 shares of common stock at an exercise price of \$1.00 per share. The shares and warrants were issued to an "accredited investor" in a transaction that did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On November 3, 2011, we issued 455,000 shares of common stock, par value \$0.001 per share, at a purchase price of \$1.00 per share pursuant to subscription agreements entered into on October 31, 2011 and November 1, 2011. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On October 28, 2011, we issued an aggregate of 112,500 shares of our common stock to the holders of the Notes issued in March 2011, in consideration for the extension of the maturity dates of such Notes. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On September 22, 2011, we issued a 10% convertible promissory note with a principal amount of \$500,000, due on March 22, 2012 and a warrant to purchase certain securities of the Company in a Target Transaction Financing (defined as "a private placement of the Company's

securities yielding gross proceeds to the Company of at least \$8,000,000"), pursuant to a Securities Purchase Agreement. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On September 21, 2011, we issued 13,914 shares of common stock to Aero Pharmaceuticals, Inc., due to the delay in filing the Company's Registration Statement on Form S-1, as required by the Asset Purchase Agreement between the Company and Aero Pharmaceuticals, Inc. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On May 16, 2011, the Company issued 7,724,000 shares of our restricted common stock to Aero and assumed Aero's liabilities in connection with the acquisition and agreed to issue additional shares on the basis of one share for (A) each dollar of current assets transferred to the Company at the closing, as set forth on the closing date balance sheet of Aero, to be delivered following the closing, and (B) each dollar of costs incurred for liquidation, certain income taxes and perfected or settled dissenters' rights of appraisal, up to a maximum of an additional 7,500,000 shares. Pursuant to the foregoing, the Company issued an additional 607,396 shares. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

On March 29, 2011, we issued 10% secured convertible promissory notes in the aggregate principal sum of \$2,250,000, due on September 29, 2011 (unless accelerated as described below) (the "Notes") and warrants (the "Warrants") to purchase certain securities of the Company in the Target Transaction (which is defined as a transaction pursuant to which the Company will acquire one or more businesses or companies approved by the holders), pursuant to a Securities Purchase Agreement Financing entered into on February 22, 2011. The Notes have an aggregate principal amount of \$2,250,000 and mature on the earlier of September 29, 2011 or the closing date of the Target Transaction Financing (such earlier date, the "Maturity Date"). The entire principal amount and any accrued and unpaid interest shall be due and payable in cash on the Maturity Date. The Notes bear interest at the rate of 10% per annum. The principal and interest will not be prepaid except in connection with the consummation of the Target Transaction Financing, in which case the holder may elect either to (i) convert all of the principal and accrued and unpaid interest then outstanding into the securities offered in the Target Transaction Financing at a price per share or unit, as the case may be, equal to 80% of the price at which such securities are sold or (ii) require the Company to repay the principal amount then outstanding and any accrued and unpaid interest in cash. In the event that the Note is not prepaid or converted prior to September 29, 2011, the Company shall pay to the holders (in the aggregate) a penalty fee equal to: (i) the principal amount of the Note divided by (ii) \$2,000,000 and multiplied by (iii) \$100,000. In the event that the Target Transaction has not closed on or prior to September 29, 2011, the Company shall pay to the holder 150% of any portion of the principal amount then outstanding plus all accrued and unpaid interest thereon. The Notes and Warrants were issued to accredited investors in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933 and Rule 506 promulgated thereunder. In March 2012, the Company repaid in full all of the outstanding principal and accrued interest due with respect to the Notes. The transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

#### **Item 6. Selected Financial Data.**

Not applicable.

#### **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements included elsewhere in this report and the information described under the caption "Risk Factors" and "Special Note Regarding Forward Looking Statements" above.

##### *Company Overview*

BioZone Pharmaceuticals, Inc., formerly known as International Surf Resorts, Inc., was incorporated under the laws of the State of Nevada on December 4, 2006 to operate as an internet-based provider of international surf resorts, camps and guided surf tours. The Company proposed to engage in the business of vacation real estate and rentals related to its surf business and it owns the website [isurfresorts.com](http://isurfresorts.com). During late February 2011, the Company began to explore alternatives to its original business plan. On February 22, 2011, the prior officers and directors resigned from their positions and the Company appointed a new President, Director, principal accounting officer and treasurer and began to pursue opportunities in medical and pharmaceutical technologies and products. On March 1, 2011, the Company changed its name to BioZone Pharmaceuticals, Inc.

On May 16, 2011, the Company acquired substantially all of the assets and assumed all of the liabilities of Aero Pharmaceuticals, Inc. pursuant to an Asset Purchase Agreement dated as of that date. Aero manufactures markets and distributes a line of dermatological products under the trade name of Baker Cummins Dermatologicals.

In December 2011, in accordance with the intent of the parties participating in the reverse merger described below, the Company transferred its 55% ownership in ISR de Mexico, S. R.L. de C. V., a Mexican corporation that was owned by the Company during the period prior to February 22, 2011, in return for and cancellation of 13,948,001 shares of the Company's common stock.

##### *Reverse Merger*

Pursuant to authoritative accounting guidance, we accounted for the purchase of the BioZone Labs Group as a "Reverse Merger", with each of BioZone Labs, Equalan and Equachem, treated as the accounting survivor.

On June 30, 2011, the Company acquired all of the outstanding shares of BioZone Laboratories, Inc. and its affiliates. BioZone Labs primarily is engaged in the business of developing and manufacturing Over the Counter ("OTC") drug products and cosmetic and beauty products on behalf of third parties. Equalan LLC ("Equalan"), related to BioZone Labs through common stock ownership, markets a line of proprietary skin care products under the brand names of Glyderm®. Equachem LLC ("Equachem") also related to BioZone Labs through common stock ownership, sells raw materials used in OTC drugs and cosmetic products. We refer to BioZone Labs, Equalan and Equachem as the "BioZone Labs Group". The BioZone Labs Group generated \$12.6 and \$15.3 million of sales during the years ended December 31, 2011 and 2010, respectively, of which \$11.3 million or 89% and \$13.9 million or 91%, respectively, were generated by BioZone Labs from its third party contract manufacturing business.



## ***Results of Operations***

*Year Ended December 31, 2011 Compared to the Year Ended December 31, 2010:*

### *Sales*

Sales for the years ended December 31, 2011 and 2010 was \$12,605,146 and \$15,253,685 respectively. The decrease in revenue of \$2,648,539 or 17.4% primarily was attributable to delays in customer orders from decreased end-user demand.

### *Cost of Sales and Gross Profit*

Cost of sales for the year ended December 31, 2011 and 2010 was \$8,639,658 and \$8,427,608, respectively, resulting in gross profit of \$3,965,488 and \$6,826,077, respectively. The gross profit percentage for the year ended December 31, 2011 and 2010 was 32% and 45% respectively. The decrease in gross profit of \$2,860,589 was primarily attributable to two items, at the end of the year we reviewed our existing inventory and determined that a portion was obsolete and unusable, as such we decided to write-off the obsolete inventory that had been valued at \$1,439,616, while the remainder of the decrease was primarily attributable to decreased end user demand for our products.

### *Operating Expenses*

We had total operating expenses of \$7,852,488 for the year ended December 31, 2011 as compared to \$6,858,122 for the year ended December 31, 2010. The increase in operating expenses of \$1,095,593 is due to an increase in general and administrative expenses \$906,711, which is primarily due to an increase in professional fees of approximately \$780,000 which consist of legal fees relating to general corporate governance, patent fees, consulting fees and audit and accounting fees as well as small increases in various other accounts, depreciation and amortization expense increased \$30,131 due to the addition of the amortization of intangible assets of \$35,350, offset by a small decrease in the depreciation of the remaining assets. Research and Development expenses increased \$158,751, which is primarily due to the opening of our research facility in Princeton, NJ and the addition of 5 new staff members.

### *Interest Expense*

We incurred interest expense of \$1,242,853 for the year ended December 31, 2011 as compared to \$439,018 for the year ended December 31, 2010. The increase in interest expense of \$803,835 is due primarily to recording a debt discount related to the derivative liability of the warrants issued in connection with the September 2011 Notes warrants of \$521,547 and the issuance of \$56,250 worth of shares to the September 2011 Notes holders in an exchange for the extension of the notes maturity were accounted for as interest expense, while the remainder of the increase was due to slightly higher interest rates on the average outstanding debt.

### *Change in value of derivative instruments*

We recorded a loss of \$281,508 on the fair value of our derivative instruments for the year ended December 31, 2011 compared to the prior year when we had no derivative instruments to value.

### *Net Loss / Income*

As a result of the foregoing, we realized a net loss of \$5,457,283 for the year ended December 31, 2011 as compared to a net loss of \$319,813 for the year ended December 31, 2010, an increase in net loss of \$5,137,470.

### *Evaluation of Disclosure Controls and Procedures*

The reason for the ineffectiveness of our disclosure controls and procedures was the result of the lack of segregation of duties and responsibilities with respect to our cash control over the disbursements related thereto. The lack of segregation of duties resulted from our limited accounting staff. Although neither management nor our independent auditors discovered any significant errors in the preparation of our financial statements, the lack of multiple levels of review and segregation of duties could lead to error or fraud and is considered a per se material weakness in internal controls over financial reporting.

### *Liquidity and Capital Resources*

As of December 31, 2011, our current assets were \$2,904,436, as compared to \$4,193,281 at December 31, 2010. As of December 31, 2011, our current liabilities were \$7,278,170, as compared to \$5,078,580 at December 31, 2010. Operating activities used net cash of \$420,953 for the year ended December 31, 2011, as compared to using net cash of \$261,420 for the year ended December 31, 2010.

During the year ended December 31, 2011, investing activities provided net cash of \$10,290, comprised primarily of cash acquired in connection with the Aero acquisition offset by purchases of property and equipment. During the year ended December 31, 2010, investing activities used net cash of \$357,610.

During the year ended December 31, 2011, cash of \$575,521 was provided by financing activities, consisting of proceeds from the issuance of convertible notes of \$2,750,000, and the sale of common stock of \$705,000. This was offset by repayment of notes payable to banks and shareholders of \$2,729,115, and payment of deferred financing fees of \$150,364, as compared to net cash provided by financing activities of \$283,098 during the comparable twelve-month period ended December 31, 2010, which consisted of net advances from a shareholder of \$375,321, offset by repayments of existing debt of \$92,223.

Our net loss for the years ended December 31, 2011 and 2010, respectively was a loss of \$5,457,310 and a loss of \$319,813. We anticipate that we will continue to generate losses from operations for the foreseeable future as we invest in research and development activities in

furtherance of our business plan of advancing our drug delivery technology. As of December 31, 2011, we had cash and cash equivalents of \$416,333 and negative working capital of \$4,373,734.

The increase in net loss of \$5,137,497 between the year ended December 31, 2010 and the year ended December 31, 2011 largely is attributable to our goal of changing the business of the Company from a vacation real estate and rentals business to a OTC and cosmetic and beauty product manufacturer and the costs associated with purchasing the Aero assets and investing in research and development activities related to our drug delivery technology.

We are in the process of reviewing our contract manufacturing cost structure to identify inefficiencies and opportunities for reductions. Also, we are reviewing our sales efforts and programs to identify opportunities for increasing sales volume. We anticipate that these efforts will reduce or eliminate ongoing losses from our contract manufacturing business and allow us to continue contract manufacturing operations for the foreseeable future.

Our current balances of cash will not meet our working capital and capital expenditure needs for the next twelve months. Because we are not currently generating sufficient cash to fund our operations and we have debt that is in default, we may need to rely on external financing to meet future operating, debt repayment and capital requirements. Any projections of future cash needs and cash flows are subject to substantial uncertainty. We can make no assurance that financing will be available in amounts or on terms acceptable to us, if at all. Further, if we issue equity securities, stockholders may experience additional dilution or the new equity securities may have rights, preferences, or privileges senior to those of existing holders of common stock, and debt financing, if available, may involve restrictive covenants that could restrict our operations or finances. If we cannot raise funds, when needed, on acceptable terms, we may not be able to continue our operations, grow market share, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, all of which could negatively impact our business, operating results, and financial condition. These conditions raise substantial doubt about our ability to continue as a going concern.

#### *Off-Balance Sheet Arrangements*

As of December 31, 2011, we had no material off-balance sheet arrangements other than operating leases.

#### *Contractual Obligations*

On June 30, 2011, the Company entered into three year executive employment agreements with three stockholders, Brian Keller, Christian Oertle and Daniel Fisher, to serve as our President, Chief Operating Officer and Executive Vice President, respectively. The agreements with Messrs. Keller and Fisher provide for annual salaries of \$200,000 each and the agreement with Mr. Oertle that provides for an annual salary of \$150,000. Pursuant to the terms of the agreements, each of these executives is eligible to participate in the Company's long term incentive compensation programs and is entitled to an annual bonus if the Company meets or exceeds criteria adopted by the Compensation Committee of the Board, subject to certain claw back rights. The agreements provide for payments of six months' severance in the event of early termination (other than for cause).

#### *Impact of Inflation*

The impact of inflation upon our revenue and income/(loss) from continuing operations during each of the past two fiscal years has not been material to our financial position or results of operations for those years because we do not maintain significant inventories whose costs are affected by inflation.

#### *Properties*

Our facilities are located in Pittsburg, California, Princeton, New Jersey, Miami, Florida and Englewood Cliffs, New Jersey.

BioZone Labs manufactures its products in a 20,000 s.f., cGMP facility owned by 580 Garcia Avenue, LLC, its consolidated VIE and fills and stores its products at a 60,000 sq. ft. rented facility located at 701 Willow Pass Road, Pittsburg, CA. The lease for the Willow Pass Road facility expires on April 30, 2015 and provides for annual rentals of approximately \$430,000.

We lease approximately 1,500 square feet of office space at 4400 Biscayne Boulevard, Miami, Florida where we employ two sales professionals for our Baker Cummins brand proprietary skin care products. The lease expires on October 31, 2012 and provides for annual rentals of approximately \$23,700. Our rent expense for our Miami facility till the end of the lease is \$20,650.

In July 2011, we entered into a lease for approximately 3,869 square feet of laboratory space in Princeton, New Jersey where we conduct research and development activities related to our proprietary drug delivery technology. The lease expires on July 20, 2016. Rent expense is approximately \$8,065 per month.

Our corporate headquarters is located at 550 Sylvan Avenue, Englewood Cliffs, New Jersey, where we lease approximately 800 square feet of office space. The lease expires on June 30, 2012. Rent expense is approximately \$1,450 per month.

#### *Seasonality*

Many of our products include cough/cold remedies, which are often sold in the winter months. Accordingly, our business is cyclical. Approximately two thirds of our revenue is generated in the second half of the calendar year.

#### **Critical Accounting Policies and Estimates**

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made, and changes in the estimate or different estimates that could have been selected could have a material impact on our consolidated results of operations or financial condition.

## *Basis of Consolidation*

The consolidated financial statements include the accounts of Biozone Pharmaceuticals, Inc. and its subsidiaries, all of which are wholly owned, its equity investment in Betazone, Inc. and its 580 Garcia Ave, a Variable Interest Entity ("VIE").

The Company considered the terms of its interest in 580 Garcia and determined that it was a variable interest entity (VIE) in accordance with ACS 810-10-55, and that it should be consolidated. As of December 31, 2011, amounts included in the consolidated assets, which are shown in Property and equipment and consolidated liabilities, which are reported in long-term debt total \$773,510 and \$2,643,435, respectively relating to 580 Garcia. The Company's involvement with the entity is limited to the lease it has to rent its facility from 580 Garcia, in which the Company is the only tenant, and the guarantee of the mortgage on the property of 580 Garcia. The Company's maximum exposure to loss, which is based on the Company's guarantee of the mortgage of 580 Garcia is \$2,643,435, which equals the carrying amount of its liability as of December 31, 2011.

The Company accounts for its investment in Betazone by the equity method since it has significant influence but not operating control over this entity. Condensed financial information of Betazone as of and for the year ended December 31, 2011 is as follows:

	2011	2010
<b>Balance sheet</b>		
Current assets	110,093	95,054
Current Liabilities	131,672	217
<b>Statement of operations</b>		
Revenues	315,346	225,266
Net income (loss)	(102,047)	122,901

## *Revenue Recognition*

BioZone Labs operates as a contract manufacturer and produces finished goods according to customer specifications. Equalan sells its merchandise directly to dermatologists and to an online retailer. Equachem operates as a reseller of pharmaceutical raw materials and licensor of intellectual property. The agreements with customers for each of the companies do not contain any rights of return other than for goods that fail to meet the specifications provided by the customer. None of the companies has experienced any significant returns from customers and accordingly, in management's opinion, no reserve for returns is provided. We record revenue when persuasive evidence of an arrangement exists, services have been rendered or product delivery has occurred, the selling price to the customer is fixed or determinable and collectability of the revenue is reasonably assured.

Revenue from the licensing of intellectual property is recorded when reported to us by the licensee.

## *Convertible Instruments*

We evaluate and account for conversion options embedded in convertible instruments in accordance with ASC 815 "Derivatives and Hedging Activities".

Applicable GAAP requires companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments according to certain criteria. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under other GAAP with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

We account for convertible instruments (when we have determined that the embedded conversion options should not be bifurcated from their host instruments) as follows: We record when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption. The embedded conversion option in connection with our convertible debt could not be exercised unless and until we completed a Qualifying Financing transaction. Accordingly, we determined based on authoritative guidance that the embedded conversion option is deemed to be a contingent conversion rather than active conversion option that did not require accounting recognition at the commitment dates of the issuances of the Notes.

## *Common Stock Purchase Warrants and Other Derivative Financial Instruments*

We classify as equity any contracts that require physical settlement or net-share settlement or provide us a choice of net-cash settlement or settlement in our own shares (physical settlement or net-share settlement) provided that such contracts are indexed to our own stock as defined in ASC 815-40 ("Contracts in Entity's Own Equity"). We classify as assets or liabilities any contracts that require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside our control) or give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). We assess classification of our common stock purchase warrants and other free standing derivatives at each reporting date to determine whether a change in classification between assets and liabilities is required.

Our derivative instruments were valued using the Black-Scholes option pricing model, using the following assumptions during the year ended December 31, 2011:

Estimated dividends	None
Expected volatility	100%
Risk-free interest rate	0.83%
Expected term	4.25 years

#### *Research and Development*

Research and development expenditures are charged to operations as incurred.

#### *Income Taxes*

We use the asset and liability method of accounting for income taxes in accordance with ASC Topic 740, “Income Taxes.” Under this method, income tax expense is recognized for the amount of: (i) taxes payable or refundable for the current year and (ii) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity’s financial statements or tax returns. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if, based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized.

ASC Topic 740.10.30 clarifies the accounting for uncertainty in income taxes recognized in an enterprise’s financial statements and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC Topic 740.10.40 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. We have no material uncertain tax positions for any of the reporting periods presented.

#### **Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that may have an impact on the Company’s accounting and reporting. The Company believes that such recently issued accounting pronouncements and other authoritative guidance for which the effective date is in the future either will not have an impact on its accounting or reporting or that such impact will not be material to its financial position, results of operations, and cash flows when implemented.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

Not applicable.

**Item 8. Financial Statements and Supplementary Data.**

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Consolidated Statements of Cash Flows for the years ended December 31, 2011 and 2010

Notes to the Consolidated Financial Statements



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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of  
Biozone Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Biozone Pharmaceuticals, Inc. as of December 31, 2011 and 2010, and the related consolidated statements of operations, changes in shareholders' deficiency and cash flows for the years ended December 31, 2011 and 2010. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company has determined that it is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Biozone Pharmaceuticals, Inc. as of December 31, 2011 and 2010 and the results of its operations and its cash flows for the years ended December 31, 2011 and 2010 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company does not have sufficient cash balances to meet working capital and capital expenditure needs for the next twelve months. In addition, as of December 31, 2011, the Company has a shareholder deficiency of \$2,769,125 and negative working capital of \$4,373,734. The continuation of the Company as a going concern is dependent on, among other things, the Company's ability to obtain necessary financing to repay debt that is in default and to meet future operating and capital requirements. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

/s/ Paritz and Company, P.A.

Hackensack, N.J.  
April 12, 2012

**BIOZONE PHARMACEUTICALS, INC.**  
**CONSOLIDATED BALANCE SHEET**

	<u>December 31, 2011</u>	<u>December 31, 2010</u>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 416,333	\$ 251,475
Account receivable net of allowance for doubtful accounts \$449,524 and \$118,356, respectively	523,039	1,397,414
Inventories	1,819,751	2,501,110
Prepaid expenses and other current assets	145,313	43,282
<b>Total current assets</b>	<u>2,904,436</u>	<u>4,193,281</u>
Property and equipment, net	3,342,447	3,262,133
Deferred financing costs, net	25,319	35,363
Goodwill	1,026,984	-
Intangibles, net	247,450	-
Investment in unconsolidated subsidiary	-	42,677
	<u>4,642,200</u>	<u>3,340,173</u>
<b>Total Assets</b>	<u>\$ 7,546,636</u>	<u>\$ 7,533,454</u>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIENCY</b>		
<b>Current liabilities:</b>		
Note payable - bank	-	2,502,863
Account payable	1,616,673	963,853
Accrued expenses and other current liabilities	1,181,852	132,889
Accrued interest	83,548	-
Notes payable - shareholder	1,099,715	1,102,926
Convertible notes payable	2,050,000	-
Deferred income tax	102,022	98,750
Derivative instruments	883,619	-
Current portion of long term debt	260,741	277,299
<b>Total current liabilities</b>	<u>7,278,170</u>	<u>5,078,580</u>
<b>Long Term Debt</b>	<u>3,037,591</u>	<u>3,044,074</u>
<b>Shareholders' deficiency</b>		
Common stock, \$.001 par value, 100,000,000 shares authorized, 55,181,165 and 44,749,999 shares issued and outstanding at December 31, 2011, and 2010, respectively	55,181	44,750
Additional paid-in capital	3,339,171	72,217
Accumulated deficit	(6,163,477)	(706,167)
<b>Total shareholders' deficiency</b>	<u>(2,769,125)</u>	<u>(589,200)</u>
<b>Total liabilities and shareholders' deficiency</b>	<u>\$ 7,546,636</u>	<u>\$ 7,533,454</u>

**BIOZONE PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Year Ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
Sales	\$ 12,605,146	\$ 15,253,685
Cost of sales	(8,639,658)	(8,427,608)
Gross profit	3,965,488	6,826,077
<b>Operating Expenses:</b>		
General and administrative expenses	7,452,864	6,617,249
Research and development expenses	399,624	240,873
<b>Total operating expenses</b>	<u>7,852,488</u>	<u>6,858,122</u>
<b>Loss from operations</b>	(3,887,000)	(32,045)
Interest expense	(1,242,853)	(439,018)
Change in fair value of derivative liability	(281,508)	-
Equity in earnings (loss) of unconsolidated subsidiary	(42,677)	55,305
<b>Loss before credit for income taxes</b>	<u>(5,454,038)</u>	<u>(415,758)</u>
Provision (benefit) for income taxes	3,272	(95,945)
<b>Net loss</b>	<u>\$ (5,457,310)</u>	<u>\$ (319,813)</u>
<b>Net loss per common share</b>	<u>\$ (0.11)</u>	<u>\$ (0.01)</u>
<b>Basic and diluted weighted average common shares outstanding</b>	<u>50,443,025</u>	<u>44,749,999</u>

**BIOZONE PHARMACEUTICALS INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Year Ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
Cash flows from operating activities		
Net (loss)	\$ (5,457,310)	\$ (319,813)
Adjustments to reconcile net (loss) to net cash used in operating activities:		
Deferred income taxes	3,272	-
Bad debt expense	326,456	554,343
Depreciation and amortization	531,844	432,566
Amortization of financing costs	160,408	7,401
Write-off obsolete inventory	1,439,616	-
Gain on change in fair value of derivative liability	281,508	-
Equity in loss (earnings) of unconsolidated subsidiary	42,677	(55,305)
Non-cash interest expense	758,044	-
Changes in assets and liabilities:		
Account receivable-trade	560,353	(650,485)
Inventories	(665,914)	(62,790)
Prepaid expenses and other current assets	(102,031)	43,879
Deferred taxes	-	(103,005)
Accounts payable	652,240	(58,845)
Accrued expenses and other current liabilities	1,047,884	(49,366)
Net cash used in operating activities	<u>(420,953)</u>	<u>(261,420)</u>
Cash flows from investing activities		
Purchase of property and equipment	(575,430)	(357,610)
Cash acquired on business combination	585,720	-
Net cash provided by (used in) investing activities	<u>10,290</u>	<u>(357,610)</u>
Cash flows from financing activities		
Proceeds from convertible debt	2,750,000	-
Payment of deferred financing costs	(150,364)	
Repayment of borrowings from noteholders	(2,725,904)	(92,223)
Proceeds from sale of common stock	705,000	
Advance from (payment to) shareholder	(3,211)	375,321
Net cash provided by financing activities	<u>575,521</u>	<u>283,098</u>
Net increase (decrease) in cash and cash equivalents	164,858	(335,932)
Cash and cash equivalents, beginning of year	<u>251,475</u>	<u>587,407</u>
Cash and cash equivalents, end of year	<u>\$ 416,333</u>	<u>\$ 251,475</u>
Supplemental disclosures of cash flow information:		
Interest paid	<u>\$ 539,616</u>	<u>\$ 439,018</u>
Conversion of convertible note payable and accrued interest to common stock	<u>\$ 509,178</u>	<u>\$ -</u>

**BIOZONE PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' DEFICIENCY**

	<b>Common Stock</b>		<b>Additional paid in capital</b>	<b>Accumulated deficit</b>	<b>Total</b>
	<b>Number of Shares</b>	<b>Amount</b>			
Balance as of December 31, 2009	44,749,999	\$ 44,750	\$ 115,248	\$ (386,354)	\$ (226,356)
Distribution				(43,031)	(43,031)
Net loss for year				(319,813)	(319,813)
Balance at December 31, 2010	<u>44,749,999</u>	<u>44,750</u>	<u>72,217</u>	<u>(706,167)</u>	<u>589,200</u>
Shares issued for acquisition	8,331,396	8,331	1,991,669		2,000,000
Proceeds from sale of common stock	955,000	955	704,045		705,000
Shares issued to extend maturity date of convertible notes payable	112,500	113	56,137		56,250
Shares issued upon conversion of convertible note payable	1,018,356	1,018	508,160		509,178
Shares issued for liquidated damages	13,914	14	6,943		6,957
Net loss for the year				(5,457,310)	(5,457,310)
Balance at December 31, 2011	<u>55,181,165</u>	<u>\$ 55,181</u>	<u>\$ 3,339,171</u>	<u>\$ (6,163,477)</u>	<u>\$ (2,769,125)</u>

## **NOTE 1 – Business**

Biozone Pharmaceuticals, Inc. (formerly, International Surf Resorts, Inc.; the “Company”, “we”, “our”) was incorporated under the laws of the State of Nevada on December 4, 2006. On March 1, 2011, we changed our name from International Surf Resorts, Inc. to Biozone Pharmaceuticals, Inc.

On May 16, 2011, we acquired substantially all of the assets and assumed all of the liabilities of Aero Pharmaceuticals, Inc. (“Aero”) pursuant to an Asset Purchase Agreement dated as of that date. Aero manufactures markets and distributes a line of dermatological products under the trade name Baker Cummins Dermatologicals (see Note 3).

On June 30, 2011, we acquired: (i) 100% of the outstanding common stock of BioZone Laboratories, Inc. (“BioZone Labs”) in exchange for 19,266,055 shares of our common stock; (ii) 100% of the outstanding membership interests of Equalan, LLC (“Equalan”) and Equachem, LLC (“Equachem”) in exchange for 1,027,523 and 385,321 shares of our common stock, respectively; and (iii) 45% of the outstanding membership interests of BetaZone, LLC (“BetaZone”) in exchange for 321,101 shares of our common stock. The acquired entities shared substantially common ownership prior to the foregoing acquisition. (We refer to BioZone Labs, Equalan, Equachem and BetaZone, collectively as the “BioZone Lab Group”).

BioZone Labs was incorporated under the laws of the State of California in 1991. Equalan was formed as a limited liability company under the laws of the State of California on January 2, 2007. Equachem was formed as a limited liability company under the laws of the State of California on March 12, 2007 under the name Chemdyn, LLC and changed its name to Equachem, LLC on July 25, 2007. BetaZone was formed as a Florida limited liability company on November 7, 2006.

The BioZone Lab Group has operated since inception as a developer, manufacturer, and marketer of over-the-counter drugs and preparations, cosmetics, and nutritional supplements on behalf of health care product marketing companies and national retailers. The Company has been developing our proprietary drug delivery technology (the “BioZone Technology”) as an enhancement for approved, generic prescription drugs that are limited due to poor stability or bioavailability or variable absorption.

The Company accounted for the acquisition of the BioZone Lab Group as a “reverse acquisition”. Accordingly, the Company is considered the legal acquirer and the BioZone Lab Group is considered the accounting acquirer. The current and future financial statements will be those of the BioZone Lab Group, and Aero from the date of acquisition.

These consolidated financial statements are presented on the basis that we will continue as a going concern concept which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our current balances of cash will not meet our working capital and capital expenditure needs for the next twelve months. In addition, as of December 31, 2011, we have a shareholder deficiency of \$2,769,125 and negative working capital of \$4,373,734. Because we are not currently generating sufficient cash to fund our operations and we have debt that is in default, we may need to rely on external financing to meet future operating, debt repayment and capital requirements. These conditions raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of the going concern uncertainty.

## **NOTE 2 - Summary of Significant Accounting Policies**

### *Basis of Consolidation*

The consolidated financial statements include the accounts of Biozone Pharmaceuticals, Inc. and its subsidiaries, all of which are wholly owned, its equity investment in Betazone, Inc. and its 580 Garcia Ave, a Variable Interest Entity (“VIE”).

The Company considered the terms of its interest in 580 Garcia and determined that it was a variable interest entity (VIE) in accordance with ACS 810-10-55, and that it should be consolidated. As of December 31, 2011, amounts included in the consolidated assets, which are shown in Property and equipment and consolidated liabilities, which are reported in long-term debt total \$773,510 and \$2,643,435, respectively relating to 580 Garcia. The Company’s involvement with the entity is limited to the lease it has to rent its facility from 580 Garcia, in which the Company is the only tenant, and the guarantee of the mortgage on the property of 580 Garcia. The Company’s maximum exposure to loss, which is based on the Company’s guarantee of the mortgage of 580 Garcia is \$2,643,435, which equals the carrying amount of its liability as of December 31, 2011.

Our significant unconsolidated subsidiary that is accounted for using the equity method of accounting is our investment in Betazone Laboratories LLC.

### *Use of Estimates*

The preparation of the financial statements in conformity with Generally Accepted Accounting Principles (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates. These estimates and assumptions include the collectability of accounts receivable and deferred taxes and related valuation allowances. Certain of our estimates, including evaluating the collectability of accounts receivable, could be affected by external conditions, including those unique to our industry, and general economic conditions. It is possible that these external factors could have an effect on our estimates that could cause actual results to differ from our estimates. We re-evaluate all of our accounting estimates at least quarterly based on these conditions and record adjustments when necessary.

### *Cash and Cash Equivalents*

We consider all short-term highly liquid investments with an original maturity at the date of purchase of three months or less to be cash

equivalents.

*Revenue Recognition*

We follow the guidance of the Securities and Exchange Commission's Staff Accounting Bulletin ("SAB") 104 for revenue recognition and Accounting Standards Codification ("ASC") Topic 605, "Revenue Recognition". The Company operates as a contract manufacturer and produces finished goods according to customer specifications. The agreements with customers do not contain any rights of return other than for goods that fail to meet the specifications provided by the customer. The Company has not experienced any significant returns from customers and accordingly, in management's opinion, no reserve for returns is provided. We record revenue when persuasive evidence of an arrangement exists, services have been rendered or product delivery has occurred, the selling price to the customer is fixed or determinable and collectability of the revenue is reasonably assured.

### *Accounts Receivable and Allowance for Doubtful Accounts Receivable*

We have a policy of reserving for uncollectible accounts based on our best estimate of the amount of probable credit losses in our existing accounts receivable. We extend credit to our customers based on an evaluation of their financial condition and other factors. We generally do not require collateral or other security to support accounts receivable. We perform ongoing credit evaluations of our customers and maintain an allowance for potential bad debts if required. We determine whether an allowance for doubtful accounts is required by evaluating specific accounts where information indicates the customers may have an inability to meet financial obligations. In these cases, we use assumptions and judgment, based on the best available facts and circumstances, to record a specific allowance for those customers against amounts due to reduce the receivable to the amount expected to be collected. These specific allowances are re-evaluated and adjusted as additional information is received. The amounts calculated are analyzed to determine the total amount of the allowance. We may also record a general allowance as necessary. Direct write-offs are taken in the period when we have exhausted our efforts to collect overdue and unpaid receivables or otherwise evaluate other circumstances that indicate that we should abandon such efforts.

### *Inventories*

Inventories are stated at the lower of cost, determined using the weighted average cost method, and net realizable value. Net realizable value is the estimated selling price, in the ordinary course of business, less estimated costs to complete and dispose of the product.

If the Company identifies excess, obsolete or unsalable items, its inventories are written down to their realizable value in the period in which the impairment is first identified. During the year ended December 31, 2011 we recorded a charge to cost of sales of \$1,439,616 relating to the write-down of inventory due to obsolescence. Shipping and handling costs incurred for inventory purchases and product shipments are recorded in cost of sales in the Company's consolidated statements of operations.

### *Fair Value Measurements*

We adopted the provisions of ASC Topic 820, "Fair Value Measurements and Disclosures", which defines fair value as used in numerous accounting pronouncements, establishes a framework for measuring fair value and expands disclosure of fair value measurements.

The estimated fair value of certain financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued expenses are carried at historical cost basis, which approximates their fair values because of the short-term nature of these instruments. The carrying amounts of our short and long term credit obligations approximate fair value because the effective yields on these obligations, which include contractual interest rates taken together with other features such as concurrent issuances of warrants and/or embedded conversion options, are comparable to rates of returns for instruments of similar credit risk.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

- Level 1 — quoted prices in active markets for identical assets or liabilities
- Level 2 — quoted prices for similar assets and liabilities in active markets or inputs that are observable
- Level 3 — inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

The warrant liabilities issued in connection with our convertible debt, classified as a level 3 liability, are the only financial liability measured at fair value on a recurring basis

We measure derivative liabilities at fair value using the Black-Scholes option pricing model with assumptions that include the fair value of the stock underlying the derivative instrument, the exercise or conversion price of the derivative instrument, the risk free interest rate for a term comparable to the term of the derivative instrument and the volatility rate and dividend yield for our common stock. For derivative instruments convertible into or exercisable for shares of our preferred stock, we considered the price per share of \$.50 paid by unrelated parties as the fair value of our common stock. For derivative instruments convertible into or exercisable for shares of our common stock, we considered the results of a valuation performed by a third party specialist and other internal analyses performed by management to determine the value of our stock at the commitment dates of applicable transactions. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. The Company has not paid dividends to date and does not expect to pay dividends in the foreseeable future due to its substantial accumulated deficit. Accordingly, expected dividends yields are currently zero. Expected volatility is based principally on an analysis of historical volatilities of similarly situated companies in the marketplace for a number of periods that is at least equal to the contractual term or estimated life of the applicable financial instrument.

We also considered the use of the lattice or binomial models with respect to valuing derivative financial instruments that feature anti-dilution price protection; however, the differences in the results are insignificant due to the low probability of triggering price adjustments in such financial instruments

### *Stock-based compensation*

We recognize compensation expense for stock-based compensation in accordance with ASC Topic 718. For employee stock-based awards, we calculate the fair value of the award on the date of grant using the Black-Scholes method for stock options and the quoted price of our common stock for unrestricted shares; the expense is recognized over the service period for awards expected to vest. For non-employee stock-based awards, we calculate the fair value of the award on the date of grant in the same manner as employee awards. However, the awards are revalued at the end of each reporting period and the pro rata compensation expense is adjusted accordingly until such time the nonemployee award is fully vested, at which time the total compensation recognized to date equals the fair value of the stock-based award as calculated on the measurement date, which is the date at which the award recipient's performance is complete. The estimation of stock-based awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from original estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised. We consider many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience.

### *Property and equipment*

Property and equipment are stated at cost less accumulated depreciation. Depreciation is provided for on a straight-line basis over the useful lives of the assets. Expenditures for additions and improvements are capitalized; repairs and maintenance are expensed as incurred.

### *Goodwill*

Goodwill represents the excess of the consideration transferred over the fair value of net assets of business purchased. Goodwill is not being amortized but is evaluated for impairment on at least an annual basis.

### *Impairment of long lived assets*

Long-lived assets are reviewed for impairment when circumstances indicate the carrying value of an asset may not be recoverable. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value.

### *Income taxes*

We use the asset and liability method of accounting for income taxes in accordance with ASC Topic 740, "Income Taxes." Under this method, income tax expense is recognized for the amount of: (i) taxes payable or refundable for the current year and (ii) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity's financial statements or tax returns. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized.

ASC Topic 740.10.30 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC Topic 740.10.40 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. We have no material uncertain tax positions for any of the reporting periods presented.

### *Convertible Instruments*

We evaluate and account for conversion options embedded in convertible instruments in accordance with ASC 815 "Derivatives and Hedging Activities".

Applicable GAAP requires companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments according to certain criteria. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under other GAAP with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

We account for convertible instruments (when we have determined that the embedded conversion options should not be bifurcated from their host instruments) as follows: We record when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption. The embedded conversion option in connection with our convertible debt could not be exercised unless and until we completed a Qualifying Financing transaction. Accordingly, we determined based on authoritative guidance that the embedded conversion option is deemed to be a contingent conversion rather than active conversion option that did not require accounting recognition at the commitment dates of the issuances of the Notes.



### *Common Stock Purchase Warrants and Other Derivative Financial Instruments*

We classify as equity any contracts that require physical settlement or net-share settlement or provide us a choice of net-cash settlement or settlement in our own shares (physical settlement or net-share settlement) provided that such contracts are indexed to our own stock as defined in ASC 815-40 ("Contracts in Entity's Own Equity"). We classify as assets or liabilities any contracts that require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside our control) or give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). We assess classification of our common stock purchase warrants and other free standing derivatives at each reporting date to determine whether a change in classification between assets and liabilities is required.

Our derivative instruments consisting of warrants to purchase our common stock were valued using the Black-Scholes option pricing model, using the following assumptions at December 31, 2011:

Estimated dividends	None
Expected volatility	100%
Risk-free interest rate	0.83%
Expected term	4.25 years

### *Concentration of Credit Risk*

Financial instruments that potentially expose us to concentrations of credit risk consist principally of cash and cash equivalents. We maintain our cash accounts at high quality financial institutions with balances, at times, in excess of Federally insured limits. Management believes that the financial institutions that hold our deposits are financially sound and therefore pose minimal credit risk.

### *Research and development*

Research and development expenditures are charged to operations as incurred

### **NOTE 3 – Aero Acquisition**

On May 16, 2011, we acquired the assets and assumed the liabilities of Aero in exchange for a total of 8,331,396 shares of our common stock valued at \$2 million. The acquisition was accounted for under the acquisition method of accounting. On September 21, 2011, the Company issued 13,914 shares of common stock to Aero Pharmaceuticals, Inc. in consideration for the delay in filing the Company's Registration Statement on Form S-1, as required in the Asset Purchase Agreement between the Company and Aero Pharmaceuticals, Inc. These shares were valued at \$0.50 per share and charged to interest expense.

The Company engaged a leading financial advisory firm specializing in corporate finance and business valuation to determine the fair value of certain identifiable intangible assets of Aero Pharmaceuticals, Inc., which were identified based on an analysis of the transaction, a review of available supporting documents, and discussions with management. The analysis focused on determining which components met the requirements for recognition as an intangible asset separate from goodwill under ASC 805, and had characteristics that allowed its value to be reasonably estimated. This analysis ultimately identified the acquired brands and customer relationships as the qualifying intangible assets subject to amortization, which were valued at \$110,000 and \$172,800, respectively. Intangible assets recognized apart from goodwill are classified as finite lived (subject to amortization) on the basis of the intangible asset's expected useful life, which was determined to be 5 years.

Accordingly, the purchase price has been allocated to the fair values of tangible and intangible assets acquired and liabilities assumed at the acquisition date as follows:

Financial assets	\$ 598,168
Inventory	92,343
Property and equipment	1,377
Financial liabilities	(1,672)
Total identifiable assets	690,216
Goodwill	1,026,984
Intangibles	282,800
	<u><u>\$2,000,000</u></u>

The following table provides unaudited pro-forma results of operations for the fiscal years ended December 31, 2011 and 2010 as if the acquisition had been consummated as of the beginning of each period presented. The pro-forma results include the effect of certain purchase accounting adjustments, such as the estimated changes in depreciation and amortization expense on the acquired intangible assets. However, pro-forma results do not include any anticipated cost savings or other effects of the planned integration of the companies. Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated, or which may occur in the future.

Pro-forma results	
Year ended December 31,	
2011	2010

Revenues	<u>\$12,712,091</u>	<u>\$15,585,000</u>
Loss before income taxes	<u>(5,515,081)</u>	<u>(516,458)</u>
Net loss per share	<u>\$ (0.11)</u>	<u>\$ (0.01)</u>

#### **NOTE 4 – Property and Equipment**

A summary of property and equipment and the estimated useful lives used in the computation of depreciation and amortization is as follows:

Fixed Asset	Useful Life	December 31, 2011	December 31, 2010
Vehicles	5 years	300,370	271,607
Furniture and Fixtures	10 years	60,936	66,195
Computers	5 years	191,206	142,978
MFG equipment	10 years	3,967,302	3,938,440
Lab Equipment	10 years	821,639	413,198
Building improvements	19 years	1,608,055	1,545,758
Building	40 years	571,141	571,141
Land	Not depreciated	380,000	380,000
		<b>7,900,649</b>	<b>7,329,317</b>
Accumulated depreciation		<b>(4,558,202)</b>	<b>(4,067,184)</b>
<b>Net</b>		<b>3,342,447</b>	<b>3,262,133</b>

#### **NOTE 5 – Equity Method Investments**

Our significant unconsolidated subsidiary that is accounted for using the equity method of accounting is our investment in Betazone Laboratories LLC. Summarized financial information for our Investment in Betazone Laboratories, LLC assuming 100% ownership interest is as follows:

	2011	2010
<b>Balance sheet</b>		
Current assets	124,462	95,054
Current Liabilities	131,672	217
<b>Statement of operations</b>		
Revenues	315,346	225,266
Net income (loss)	(102,047)	122,901

In 2011, when the company's share of losses equaled the carrying value of its investment, the equity method of accounting was suspended, and no additional losses were charged to operations. The company's unrecorded share of losses for 2011 totaled \$3,245.

#### **NOTE 6 – Convertible Notes Payable**

##### *The “March 2011 Notes”*

On March 29, 2011, the Company sold 10% secured convertible promissory notes in the amount of \$2,250,000, (the “March 2011 Notes”) and warrants (the “March Warrants”) to purchase securities of the Company in the Target Transaction Financing (as defined below), pursuant to a Securities Purchase Agreement entered into on February 22, 2011 (the “Securities Purchase Agreement” and the “Private Placement”).

The March 2011 Notes, extended as described below, originally were scheduled to mature on the earlier of October 29, 2011 or the closing date of the Target Transaction Financing (such earlier date, the “Maturity Date”). The entire principal amount and any accrued and unpaid interest was due and payable in cash on the Maturity Date.

We recorded the liability for the March 2011 Notes at an amount equal to the full consideration received upon issuance, without considering the Warrant value because the determination of the number of warrants and the exercise price of the warrants is dependent on the closing date of, and the price of securities issued in the Target Transaction Financing, which has yet to take place.

Effective October 28, 2011, the purchasers of the March 2011 Notes (the “Note Holders”) agreed to extend the maturity date of the Notes (the “Extension Agreement”) to October 29, 2011 (the “New Maturity Date”) (see Note 5). As consideration for the agreement by the Note Holders to enter into the Extension Agreement, the Company (i) issued to the Note Holders an aggregate of 112,500 shares of its common stock, par value \$0.001 per share and (ii) paid to the Investors, an aggregate of \$129,000 of interest for the period beginning on February 28, 2011 (the date the Note Holders placed the principal amount in escrow) and ending on March 28, 2011. The Company agreed to provide piggyback registration rights with respect to the 112,500 shares on the same terms and conditions provided for the registrable securities in the Registration Rights Agreement contained in the Private Placement.

The Company agreed that if it fails to repay the March 2011 Notes on or before the New Maturity Date, then in addition to the interest due under the March 2011 Notes, the Company would pay an additional 2% (annualized) for each 30 day period all or any portion of the principal or accrued interest remain unpaid, subject to a maximum aggregate interest rate of 20% (the sum of the 10% interest rate plus 2% for each 30 day delay period), with such 2% being calculated on the full principal amount regardless of whether any portion thereof has been repaid by the Company and such full amount accruing as of the day following the New Maturity Date and then upon each 30 day anniversary of the New Maturity Date.

On December 8, 2011 the Company repaid \$200,000 to one of the note holders.

In March 2012, the Company repaid in full all of the outstanding principal and accrued interest due with respect to the March 2011 Notes.

*The “September 2011 Note”*

On September 22, 2011, the Company issued a 10% unsecured convertible promissory note with a principal amount of \$500,000, due on March 22, 2012 (the “September 2011 Note”) and a warrant (the “September Warrant”) to purchase certain securities of the Company in the Target Transaction Financing, pursuant to a Securities Purchase Agreement entered into on that date (the“Securities Purchase Agreement”).

On November 30, 2011, the note and accrued interest were converted into 1,018,356 shares of common stock, par value \$0.001 per share. The Company also issued the holder a warrant to purchase 500,000 shares of common stock at an exercise price of \$1.00 per share.

**NOTE 7 – Notes Payable – Shareholder**

This amount is due to our former Executive Vice President for advances made to the Company, bears interest at a weighted average rate of approximately 10% and is due on demand. The Company is in dispute with the shareholder as to the balance due but has recorded the full amount claimed by the shareholder.

## NOTE 8 – Long Term Debt

	Year ended December 31,	
	2011	2010
<b>Notes payable of Biozone Labs</b>		
Capitalized lease obligations bearing interest at rates ranging from 8.6% to 16.3%, payable in monthly installments of \$168 to \$1,589, inclusive of interest	\$ 307,255	\$ 213,510
City of Pittsburg Redevelopment Agency, 3% interest, payable in monthly installments of \$3,640 inclusive of interest	257,639	304,721
Other	90,000	100,000
<b>Notes payable of 580 Garcia Properties</b>		
Mortgage payable of 580 Garcia collateralized by the land and building payable in monthly installments of \$20,794, inclusive of interest at 7.24% per annum	2,643,438	2,703,142
Less: current portion	\$ 3,298,332	\$ 3,321,373
	260,741	277,299
	<u>3,037,591</u>	<u>3,044,074</u>

Long-term debt (excluding capital leases) matures as follow:

12/31/2012	106,797
12/31/2013	112,434
12/31/2014	118,446
12/31/2015	124,766
12/31/2016	131,695
Thereafter	2,396,940

Future minimum annual lease payments for capital leases in effect as of December 31, 2011 are as follows:

12/31/2012	153,944
12/31/2013	69,316
12/31/2014	58,214
12/31/2015	25,780
12/31/2016	-
Thereafter	-

## NOTE 9 – Warrants

On March 29, 2011 and September 22, 2011, the Company issued warrants to purchase securities of the Company in the Target Transaction Financing (Note 5). The Warrants are immediately exercisable and expire five years after the date of issue. Each Warrant has an initial exercise price of 120% of the price of the securities sold in the Target Transaction Financing (the “Financing Share Price”). The Warrant entitles the holder to purchase the number of shares of Common Stock and/or other securities, including units of securities, sold in the Target Transaction Financing equal to the Warrant Coverage (as defined herein) (a) multiplied by the principal amount of the Note (the “Purchase Price”) and (b) divided by the Financing Share Price. “Warrant Coverage” means (i) 50% if closed on or prior to 120 days, (ii) 75% if closed after 120 days but before 150 days and (iii) 100%, if closed after 150 days after the closing of the Private Placement. The Warrant is exercisable in cash or by way of a “cashless exercise” during any period that a registration statement covering the shares of Common Stock and/or other securities issuable upon exercise of the Warrant, or an exemption from registration, is not available. The exercise price of the Warrant is subject to a “ratchet” anti-dilution adjustment for a period of one year from the closing of the Private Placement. This adjustment provides that, in the event that the Company issues certain securities at a price lower than the then applicable exercise price, the exercise price of the Warrant will be immediately reduced to equal the price at which the Company issued the securities.

The value of the warrants have been recorded as a derivative liability.

## NOTE 10 – Income Taxes

The reconciliation of income tax benefit at the U.S. statutory rate of 34% for the years ended December 31, 2011 and 2010 to the Company’s effective tax rate is as follows:

	Year ended December 31,	
	2011	2010
U.S. federal statutory rate	-34.0%	-34.0%
State income tax, net of federal benefit	-6.0%	-6.0%
Permanent differences	8.7%	0.0%
Increase in valuation allowance	31.9%	28.0%
Income tax provision (benefit)	<u>0.6%</u>	<u>-12.0%</u>

The benefit for income tax is summarized as follows:

	Year ended December 31,	
	2011	2010
Federal:		

Current	\$ -	\$ -
Deferred	(1,693,454)	(81,553)
State and local:		
Current	-	
Deferred	(298,845)	(14,392)
Change in valuation allowance	1,995,571	-
Income tax provision (benefit)	<u>\$ 3,272</u>	<u>\$ (95,945)</u>

The tax effects of temporary differences that give rise to the Company's net deferred tax liability as of December 31, 2011 and 2010 are as follows:

	Year ended December 31,	
	2011	2010
<b>Deferred tax assets</b>		
Net operating losses	\$ 1,003,188	\$ 274,138
Allowance for doubtful accounts	<u>179,810</u>	<u>47,342</u>
	1,182,998	321,480
Less: valuation allowance	(1,182,998)	(274,138)
	-	47,342
<b>Deferred tax liability</b>		
Depreciation	<u>102,022</u>	<u>(146,092)</u>
Total deferred tax liability	<u>\$ 102,022</u>	<u>\$ (98,750)</u>

As of December 31, 2011 and 2010, the Company had approximately \$2,500,000 and \$685,000 of federal and state net operating loss carryovers ("NOLs") which begin to expire in 2028. Utilization of the NOLs may be subject to limitation under the Internal Revenue Code Section 382 should there be a greater than 50% ownership change as determined under regulations. The change in ownership occurred of the Company that in June 2011 resulted in an annual limitation on the usage of the Company's pre-acquisition net operating loss carryforwards.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Based on the assessment, management has established a full valuation allowance against all of the deferred tax asset relating to NOLs for every period because it is more likely than not that all of the deferred tax asset will not be realized.

The Company files U.S. federal and states of California tax returns that are subject to audit by tax authorities beginning with the year ended December 31, 2008. The Company's policy is to classify assessments, if any, for tax and related interest and penalties as tax expense. We do not currently have any ongoing tax examinations.

#### **NOTE 11 – Concentrations**

Approximately, 27% and 9% of the Company's sales for the year ended December 31, 2011 were made to two customers. These customers accounted for 30% and 11% of the Company's sales for the year ended December 31, 2010.

#### **NOTE 12 – Contingencies**

##### *Employment Agreements*

On June 30, 2011, the Company entered into three year executive employment agreements with three stockholders, Brian Keller, Christian Oertle and Daniel Fisher, to serve as our President, Chief Operating Officer and Executive Vice President, respectively. The agreements with Messrs. Keller and Fisher provide for annual salaries of \$200,000 each and the agreement with Mr. Oertle provides for an annual salary of \$150,000. Pursuant to the terms of the agreements, each of these stockholders is eligible to participate in the Company's long term incentive compensation programs and is entitled to an annual bonus if the Company meets or exceeds criteria adopted by the Compensation Committee of the Board, subject to certain claw back rights. The agreements provide for payments of six months' severance in the event of early termination (other than for cause).

##### *Leases*

The Company leases its facilities under operating leases that expire at various dates. Total rent expense under these leases is recognized ratably over the initial renewal period of each lease. The following table presents future minimum lease commitments under non-cancelable operating leases at December 31, 2011:

2012	\$ 466,414
2013	442,623
2014	442,623
2015	211,022
2016	63,481
Thereafter	-
	<u>\$1,626,163</u>

Total rent and related expenses under operating leases were \$411,551 and \$403,669 for the years ended December 31, 2011, 2010 respectively. Operating lease obligations after 2011 relate primarily to office facilities

#### Litigation

We are not involved in any pending legal proceeding or litigation that we believe would have a material impact upon our business or results of operations.

An action was initiated recently against BioZone Labs, BioZone Pharma and a former officer and director in the United States District Court for the District of Maryland. The complaint in that matter, which was filed on March 19, 2012, alleges breach of contract and other commercial wrongdoing in connection with a single purchase order issued during early 2010 relating to the development of certain over the counter products to treat cough and cold symptoms. Although the complaint does not specify the amount of plaintiff's alleged monetary damages, plaintiff's payment associated with the purchase order was less than \$190,000. Accordingly, although our investigation into the matter is still in its earliest stages, we do not believe it will have a material impact on our business. In addition, to the best of our knowledge, no governmental authority is contemplating any proceeding to which we are a party, which would reasonably be likely to have a material adverse effect on our business or results of operations.

BioZone Laboratories, Inc. v. ComputerShare Trust Co., N.A. and Cardium Therapeutics, Inc. District Court, State of Colorado, County of Jefferson, Case No. 2012CV406

The Company commenced the above action, by filing of a Summons and Complaint, on February 2, 2012 for declaratory relief, specific performance and monetary damages against Defendants ComputerShare Trust Co., N.A. ("ComputerShare") and Cardium Therapeutics, Inc. ("Cardium") (collectively, the "Defendants"). This action arises from, inter alia, the failure of ComputerShare, which was acting as an escrow agent in connection with the Company's purchase of Cardium stock, to deliver such stock to the Company as required by an Escrow Agreement entered into between the Company and Defendants. By Order, dated March 30, 2012, the Court dismissed this action on the ground that venue was improper in Colorado.

**NOTE 13 - Subsequent Events**

On January 11, 2012, the Company sold an aggregate of 600,000 units (the "Units") with gross proceeds to the Company of \$300,000. Each Unit was sold for a purchase price of \$0.50 per Unit and consists of: (i) one share of Common Stock and (ii) a four-year warrant to purchase 300,000 shares of Common Stock purchased at an exercise price of \$1.00 per share, subject to adjustment upon the occurrence of certain events. The warrants may be exercised on a cashless basis after twelve (12) months from the date of closing, if there is no effective registration statement covering the shares of Common Stock issuable upon exercise of the Warrant.

On January 25, 2012, the Company sold an aggregate of 700,000 units (the “Units”) with gross proceeds to the Company of \$350,000.

Each Unit was sold for a purchase price of \$0.50 per Unit and consists of: (i) one share of Common Stock and (ii) a four-year warrant to purchase 350,000 shares of Common Stock at an exercise price of \$1.00 per share, subject to adjustment upon the occurrence of certain events. The warrants may be exercised on a cashless basis after twelve (12) months from the date of closing, if there is no effective registration statement covering the shares of Common Stock issuable upon exercise of the Warrant.

On January 30, 2012, the Board of Directors of the Company removed Daniel Fisher from his position as the Company’s Executive Vice President. Mr. Fisher resigned from his position as Director on February 3, 2012.

On February 24, 2012, the Company entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”) with a purchaser (the “Buyer”) pursuant to which the Company sold (i) \$1,700,000 of its 10% secured convertible promissory note (the “Note”) due two years from the date of issuance (the “Maturity Date”) and (ii) warrants (the “Warrants”) to purchase 8,500,000 shares of the Company’s common stock at an exercise price of \$0.40 per share for gross proceeds to the Company of \$1,700,000. On February 28, 2012 and February 29, 2012, the Company sold an additional \$600,000 of its Notes and issued Warrants to purchase an additional 3,000,000 shares of the Company’s common stock to additional Buyers for gross proceeds to the Company of \$600,000.

The entire principal amount and any accrued and unpaid interest on the Notes shall be due and payable in cash on the Maturity Date. The Notes bear interest at the rate of 10% per annum. The Notes are convertible into shares of the Company’s common stock at an initial conversion price of \$0.20 per share, subject to adjustment. The Company may prepay any outstanding amount due under the Notes, in whole or in part, prior to the Maturity Date. The Notes are subject to certain “Events of Defaults” which could cause all amounts due and owing thereunder to become immediately due and payable. Among other things, the Company’s failure to pay any accrued but unpaid interest when due, the failure to perform any obligation under the Transaction Documents (as defined herein) or if any representation or warranty made by the Company in connection with the Transaction Documents shall prove to have been incorrect in any material respect, shall constitute an Event of Default under the Transaction Documents.

The Warrant is immediately exercisable and expires ten years after the date of issuance. The Warrant has an initial exercise price of \$0.40 per share. The Warrant is exercisable in cash or, while a registration statement covering the shares of Common Stock issuable upon exercise of the Warrant, or an exemption from registration, is not available, by way of a “cashless exercise”.

The Company is prohibited from effecting a conversion of the Notes or exercise of the Warrants, to the extent that as a result of such conversion or exercise, the Buyer would beneficially own more than 4.99% (subject to waiver) in the aggregate of the issued and outstanding shares of the Company’s common stock, calculated immediately after giving effect to the issuance of shares of common stock upon conversion of such Note or exercise of such Warrant, as the case may be.

In connection with the sale of the Notes and the Warrants, the Company and the collateral agent for the Buyers entered into a Pledge and Security Agreement (the “Security Agreement” and, collectively with the Securities Purchase Agreement, the Note and the Warrant, the “Transaction Documents”) pursuant to which all of the Company’s obligations under the Notes are secured by a first priority perfected security interest in all of the tangible and intangible assets of the Company, including all of its ownership interest in its subsidiaries.

On February 27, 2012, the Company issued warrants to purchase 1,000,000 shares of the Company’s common stock at an exercise price of \$0.60 per share to the former holders of the March 2011 Notes described in Note 6 – Convertible Notes Payable in connection with the repayment of those notes.

On March 1, 2012, the Company issued 455,000 shares of its common stock to certain individuals who previously purchased shares of the Company’s common stock on November 3, 2011 at a purchase price of \$1.00 per share.

On March 13, 2012, the “Company sold a 10% senior convertible promissory note (the “Note”) to an accredited investor (the “Investor”) for an aggregate purchase price of \$1,000,000. The principal amount of the Note is payable in cash on such dates and in such amounts as set forth in the Note, based on the receipt of proceeds from sales to a certain vendor (the “Vendor Proceeds”). The last date of such scheduled payment shall be referred to as the “Final Maturity Date”.

The Note bears interest at the rate of 10% per annum. The Company may prepay any outstanding amounts owing under the Note, in whole or in part, at any time prior to the Final Maturity Date. The entire remaining principal amount and all accrued but unpaid or unconverted interest thereof, shall be due and payable on the earliest of (1) the Final Maturity Date, (2) the consummation of a financing by the Company resulting in net proceeds equal to or greater than 1.5 times the remaining outstanding unconverted principal amount hereunder and (3) the occurrence of an Event of Default (as defined in the Note). The Note is convertible into shares of the Company’s common stock at an initial conversion price of \$1.50 per share.

The Company is prohibited from effecting a conversion of the Note, to the extent that as a result of such conversion, the Investor would beneficially own more than 4.99% (subject to waiver) in the aggregate of the issued and outstanding shares of the Company’s common stock, calculated immediately after giving effect to the issuance of shares of common stock upon conversion of the Note.

All of the Company’s obligations under the Note are secured by a first priority security interest in the Vendor Proceeds.

Certain holders of senior secured indebtedness of the Company agreed to subordinate their security interest in the Vendor Proceeds to the interest of the Investor under the Note.

**Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.**

None.

**Item 9A. Controls and Procedures.****Controls and Procedures**

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as of December 31, 2011, the fiscal year end covered by this report, our management concluded its evaluation of the effectiveness of the design and operation of our disclosure controls and procedures.

Disclosure controls and procedures refer to controls and other procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating and implementing possible controls and procedures.

Our management does not expect that our disclosure controls and procedures will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the fiscal year ending December 31, 2011, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934. Based upon our evaluation regarding the fiscal year ending December 31, 2011, our management, including Mr. Elliot Maza, our Chief Executive Officer and Chief Financial Officer, has concluded that its disclosure controls and procedures were not effective due to insufficient personnel to properly prepare, implement and monitor adequate controls and procedures.

**Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act. Our management is also required to assess and report on the effectiveness of our internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"). Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework. During our assessment of the effectiveness of internal control over financial reporting as of December 31, 2011, management identified significant deficiencies related to insufficient personnel to properly segregate duties. Therefore, our internal controls over financial reporting were not effective as of December 31, 2011.

A material weakness (within the meaning of PCAOB Auditing Standard No. 5) is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for oversight of the company's financial reporting.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the fourth quarter of the year ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

**Item 9B. Other Information.**

None.



## PART III

### Item 10. Directors, Executive Officers and Corporate Governance.

#### EXECUTIVE OFFICERS AND DIRECTORS

Name	Age	Position
Roberto Prego-Novo	68	Chairman
Elliot M. Maza	56	Chief Executive Officer, Chief Financial Officer and Secretary and Director
Brian Keller	55	President, Chief Scientific Officer and Director
Christian Oertle	39	Chief Operating Officer

*Roberto Prego-Novo, Chairman.* Mr. Prego-Novo was appointed to our board of directors and as our President, Principal Accounting Officer and Secretary on February 24, 2011. Mr. Prego-Novo resigned from all executive positions with us and was appointed as our Chairman on June 30, 2011. Since 1974, Mr. Novo has served as the President of Laboratorios Elmor S.A., a Venezuelan pharmaceutical company. Mr. Novo served as the Vice President, Latin America, of Teva Pharmaceutical Industries Limited from 2006 to 2010 and as the Vice President, Latin America, of IVAX Corporation from 2006 to 2008. Mr. Prego-Novo served as our President and Principal Accounting Officer from February 24, 2011 to June 30, 2011. Mr. Prego-Novo was chosen to be a director based on his extensive pharmaceutical industry experience. We believe Mr. Prego-Novo's qualifications to serve as our chairman include his years of experience as an executive of large pharmaceutical companies, in particular at Teva Pharmaceutical Industries Limited, one of the five largest manufacturers of generic pharmaceutical products in the world. We expect that Mr. Prego-Novo will be able to draw on his knowledge of the generic pharmaceuticals industry to help us develop our branded generic pharmaceutical business.

*Elliot M. Maza, J.D., C.P.A., Chief Executive Officer, Chief Financial Officer and Secretary and Director.* Elliot Maza serves as our Chief Executive Officer, Chief Financial Officer and Secretary. Mr. Maza was appointed as our Interim Chief Executive Officer, Chief Financial Officer and Secretary on May 16, 2011. Mr. Maza was appointed as our Chief Executive Officer on August 2, 2011. On February 24, 2012, the Board of Directors of the Company appointed Elliot Maza as a director of the Company. From May 2006 until the present time, Mr. Maza has served in several management positions at Intellect Neurosciences, Inc., a biotechnology company focused on the development of therapeutics for Alzheimer's disease. Mr. Maza served as the Executive Vice President of Intellect Neurosciences, Inc. from May 2006 to March 2007, as President from March 2007 until October 2011, and as Chief Financial Officer from May 2006 through the present time. Mr. Maza was also appointed to the board of directors of Intellect Neurosciences, Inc. on June 26, 2007. From December 2003 to May 2006, Mr. Maza served as Chief Financial Officer of Emisphere Technologies, Inc., a biopharmaceutical company specializing in oral drug delivery. He was a partner at Ernst and Young, LLP from March 1999 to December 2003. During the period from May 1989 to March 1999, Mr. Maza served as an Associate and subsequently Vice President in the Fixed Income divisions of Goldman Sachs, Inc. and JP Morgan Securities, Inc. Mr. Maza practiced tax and corporate law at Sullivan and Cromwell in New York from September 1985 to April 1989. Mr. Maza has served on the Board of Directors and as Chairman of the Audit Committee of several biotech and pharmaceutical companies. Mr. Maza received his B.A. degree from Touro College in New York and his J.D. degree from the University of Pennsylvania Law School. He is a licensed C.P.A. and a member of the Bar in the states of New York and New Jersey. Mr. Maza was appointed as a director of the Company based on his experience as a senior executive in several biotech and biopharma companies and his positions as chief executive officer and chief financial officer of the Company.

*Brian Keller, Pharm.D., President, Chief Scientific Officer and Director.* Dr. Keller has served as our President, Chief Scientific Officer and Director on June 30, 2011. Dr. Keller co-founded BioZone Laboratories, Inc. with Mr. Daniel Fisher in 1989, and has served as its Executive Vice President and Chief Scientific Officer since that time. Dr. Keller is the inventor of the Company's QuSomes, LiquaVail, and HyperSorb technology. Dr. Keller graduated from University of California, San Diego, in 1979 with a BS in biology, and received his doctorate in pharmacy from University of California, San Francisco, in 1983. Dr. Keller is a registered pharmacist. We believe Dr. Keller's qualifications to serve as a director include his management and industry experience gained as the co-founder of BioZone Laboratories, Inc., one of our subsidiaries, as well as his general scientific knowledge.

*Christian Oertle, Chief Operating Officer.* Mr. Oertle has served as our Chief Operating Officer since June 30, 2011. From May 2003 until the present time, Mr. Oertle has served as the General Manager of BioZone Laboratories, Inc. From May 2000 to May 2003, Mr. Oertle served as the Director of Product Research and Development for BioZone Laboratories, Inc. Prior to May 2000 Mr. Oertle worked as a formulation chemist at BioZone Laboratories, Inc; Bertek Pharmaceuticals, a division of Mylan Laboratories (formerly Penederm Incorporated); and Alza Corporation. Mr. Oertle holds a Bachelor of Science Degree in Chemistry from University of California at Davis

#### Family Relationships

There are no family relationships between the officers and directors listed above.

#### Employment Agreements

On June 30, 2011, we entered into an employment agreement with Dr. Keller pursuant to which Dr. Keller will serve as our President and Chief Scientific Officer for a period of three years in consideration for an annual salary of \$200,000. Pursuant to the terms of his employment agreement, Dr. Keller shall be eligible to participate in the Company's long term incentive compensation programs and shall be entitled to an annual bonus if the Company meets or exceeds criteria adopted by the Board and subject to certain claw back rights.



In the event Dr. Keller's employment is terminated due to his death or disability, his estate or his beneficiaries, as the case may be, shall be entitled to earned and unpaid base salary through the date of death or date of termination of his employment and all accrued and unpaid vacation time and all other additional benefits then due or earned in accordance with the Company's applicable plans and programs. In the event the Company terminates Dr. Keller's employment for cause, he shall be entitled to earned and unpaid base salary through the termination date and all accrued and unpaid vacation time and all other additional benefits then due or earned in accordance with the Company's applicable plans or programs. In the event Dr. Keller's employment is terminated without cause, other than due to Dr. Keller's death or disability, Dr. Keller shall be entitled to i) earned and unpaid base salary through the termination date, ii) the sum of his base salary, at the annualized rate in effect on the termination date (or, in the event a reduction in base salary is a basis for a termination by Dr. Keller for good reason, then the base salary in effect immediately prior to such reduction) divided by 12, and which such monthly payments are to be paid to Dr. Keller for a period of 6 months but not to extend beyond the last day of his employment period (the "Severance Period"), iii) any outstanding stock options or shares of restricted stock which are unvested shall vest and Dr. Keller shall have the right to exercise any vested stock options during the Severance Period or for the remainder of the exercise period, iv) continued participation in all medical, health and life insurance plans at the same benefit level at which he was participating on the date of the termination of his employment until the earlier of the end of the Severance Period or the date, or dates, he receives equivalent coverage and benefits under the plans and programs of a subsequent employer and (v) all accrued and unpaid vacation and all other additional benefits then due or earned in accordance with the Company's applicable plans or programs. Upon termination of Dr. Keller's employment, he shall not be entitled to any severance payments or severance benefits from the Company or any payments by the Company on account of any claim by him of wrongful termination, including claims under any federal, state or local human and civil rights or labor laws, other than the payments and benefits provided in the employment agreement.

On June 30, 2011, we entered into an employment agreement with Christian Oertle pursuant to which Mr. Oertle will serve as our Chief Operating Officer for a period of three years in consideration for an annual salary of \$150,000. Pursuant to the terms of his employment agreement, Mr. Oertle shall be eligible to participate in the Company's long term incentive compensation programs and shall be entitled to an annual bonus if the Company meets or exceeds criteria adopted by the Board which shall be subject to certain claw back rights. Mr. Oertle's employment agreement has the same termination and severance provisions as Dr. Keller's employment agreement.

On June 30, 2011, we entered into an employment agreement with Mr. Daniel Fisher, formerly Executive Vice President and Director of the Company, pursuant to which Mr. Fisher was to serve as our Executive Vice President for a period of three years in consideration for an annual salary of \$200,000 and would be eligible to participate in the Company's long term incentive compensation programs and shall be entitled to an annual bonus if the Company meets or exceeds criteria adopted by the Board which shall be subject to certain claw back rights. Mr. Fisher's employment agreement has the same termination and severance provisions as Dr. Keller's agreement and Mr. Oertle's agreement. On January 30, 2012, Mr. Fisher was removed from his position as Executive Vice President for cause. Pursuant to his employment agreement, Mr. Fisher is entitled to accrued salary through the date of termination.

#### **Director or Officer Involvement in Certain Legal Proceedings**

Our directors and executive officers were not involved in any legal proceedings as described in Item 401(f) of Regulation S-K in the past ten years except as set forth in Item 3 — Legal Proceedings — herein.

#### **Directors' and Officers' Liability Insurance**

The Company has obtained directors' and officers' liability insurance insuring its directors and officers against liability for acts or omissions in their capacities as directors or officers. Such insurance also insures us against losses which we may incur in indemnifying our officers and directors. In addition, the Company may enter into indemnification agreements with key officers and directors and such persons shall also have indemnification rights under applicable laws, and the Company's Articles of Incorporation and Bylaws.

#### **Board Independence**

We currently have three directors serving on our Board of Directors: Mr. Prego-Novo, Dr. Keller and Mr. Maza. We are not listed on a national securities exchange and are not subject to any director independence standards. Using the definition of independence set forth in the rules of the American Stock Exchange, none of our directors would be considered an independent director of the Company.

#### **Corporate Governance**

##### **Meetings and Committees of the Board of Directors**

Our Board of Directors held one formal meeting during the year ended December 31, 2011.

We currently do not maintain any committees of the Board of Directors. Given our size and the development of our business to date, we believe that the board through its meetings can perform all of the duties and responsibilities which might be contemplated by a committee.

Except as may be provided in our bylaws, we do not currently have specified procedures in place pursuant to which whereby security holders may recommend nominees to the Board of Directors.

#### **Board Leadership Structure and Role in Risk Oversight**

Although we have not adopted a formal policy on whether the Chairman and Chief Executive Officer positions should be separate or combined, we have traditionally determined that it is in the best interests of the Company and its shareholders to separate these roles because it allows us to separate the strategic and oversight roles within our board structure.

Our Board of Directors is primarily responsible for overseeing our risk management processes. The Board of Directors receives and

reviews periodic reports from management, auditors, legal counsel, and others, as considered appropriate regarding our company's assessment of risks. The Board of Directors focuses on the most significant risks facing our company and our company's general risk management strategy, and also ensures that risks undertaken by our company are consistent with the Board's appetite for risk. While the Board oversees our company, our company's management is responsible for day-to-day risk management processes. We believe this division of responsibilities is the most effective approach for addressing the risks facing our company and that our Board leadership structure supports this approach.

## **Code of Ethics**

We have not yet adopted a Code of Ethics although we expect to as we develop our infrastructure and business.

## **Board Diversity**

While we do not have a formal policy on diversity, our Board considers diversity to include the skill set, background, reputation, type and length of business experience of our Board members as well as a particular nominee's contributions to that mix. Although there are many other factors, the Board seeks individuals with experience on public company boards as well as experience with advertising, marketing, legal and accounting skills.

## **Board Assessment of Risk**

Our risk management function is overseen by our Board. Our management keeps our Board apprised of material risks and provides our directors access to all information necessary for them to understand and evaluate how these risks interrelate, how they affect the Company, and how management addresses those risks. Mr. Elliot Maza, a director and our Chief Executive Officer and Chief Financial Officer works closely together with the Board once material risks are identified on how to best address such risk. If the identified risk poses an actual or potential conflict with management, our independent directors may conduct the assessment. The Board focuses on these key risks and interfaces with management on seeking solutions.

## **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors, executive officers, and persons who own more than 10% of our common stock to file reports of ownership and changes in ownership of our common stock with the SEC. Based on the information available to us during 2011, we believe that all applicable Section 16(a) filing requirements were met on a timely basis.

## **Item 11. Executive Compensation.**

### **Summary Compensation Table**

The table below sets forth, for the last two fiscal years, the compensation earned by the executive officers listed below. No other executive officers had annual compensation in excess of \$100,000 during the last fiscal year.

Name and Principal Position	Year Ended	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	All Other Compensation (\$)(1)	Total (\$)
Elliot Maza (2)	2010	0	0	0	0	0	0	0
	2011	38,462						38,462
Brian Keller (3)	2010	100,000	0	0	0	0	24,771	124,771
	2011	100,000					35,712	135,712
Daniel Fisher (4)	2010	112,000	0	0	0	3,360 (5)	35,149	150,509
	2011	112,000					44,702	156,702
Christian Oertle (6)	2010	100,000	0	0	0	0	5,498	105,498
	2011	100,000					4,223	104,223
Roberto Prego-Novoo (7)	2010	0	0	0	0	0	0	0
	2011	0	0	0	0	0	0	0
Eduardo Biancardi President, Secretary, CFO (8)	2010	0	0	0	0	0	0	0
	2011	0	0	0	0	0	0	0
Timothy Neely, Chief Operating Officer (9)	2010	0	0	0	0	0	0	0
	2011	0	0	0	0	0	0	0



1. The compensation amount set forth represents reimbursement of medical and dental insurance, life insurance, and auto expenses.
2. Appointed as Interim Chief Executive Officer, Chief Financial Officer and Secretary on June 30, 2011, as Chief Executive Officer on August 2, 2011 and as a director on February 24, 2012.
3. Appointed as President and Chief Scientific Officer on June 30, 2011.
4. Appointed as Executive Vice President on June 30, 2011. Removed from his position as Executive Vice President on January 30, 2012 and resigned from his position as Director on February 3, 2012.
5. The compensation amount set forth represents Company contributions to Mr. Fisher's IRA account.
6. Appointed as Chief Operating Officer on June 30, 2011
7. Appointed as President on February 24, 2011. Resigned from all officer positions and appointed as Chairman of the Board of Directors on June 30, 2011.
8. Resigned from all positions on February 24, 2011
9. Resigned from all positions on February 22, 2011

### **Outstanding Equity Awards at Fiscal Year-End**

There were no outstanding equity awards issued to our named executive officers as of December 31, 2011.

### **Director Compensation**

The Company does not have any compensation arrangements for members of its Board of Directors.

### **Stock Incentive Plan**

As of December 31, 2011, the Company had not adopted a stock incentive plan.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The following tables set forth certain information as of April 16, 2012 regarding the beneficial ownership of our common stock, by (i) each person or entity who, to our knowledge, owns more than 5% of our common stock; (ii) our executive officers; (iii) each director; and (iv) all of our executive officers and directors as a group. Unless otherwise indicated in the footnotes to the following table, each person named in the table has sole voting and investment power and that person's address is c/o BioZone Pharmaceuticals, Inc., 550 Sylvan Avenue, Suite 101, Englewood Cliffs, NJ 07632. Shares of common stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of April 16, 2012, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the stockholder holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other stockholder.

<b>Name of Beneficial Owner</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percentage Beneficially Owned (1)(2)</b>
5% Owners:		
Aero Pharmaceuticals, Inc. 4400 Biscayne Boulevard Miami, FL 33137	8,345,310	12.1%
Frost Gamma Investments Trust (2) 4400 Biscayne Boulevard Miami, FL 33137	3,606,500	5.2%
Nian Wu 103 Sassafras Court, North Brunswick, NJ	6,650,000 (5)	9.7%
Executive Officers and Directors		
Brian Keller	6,650,000 (5)	11.8%
Christian Oertle	1,050,000 (5)	1.9%
Elliot Maza	0	
Roberto Prego-Novo (3)	2,500,000	4.4%
All executive officers and directors as a group (4 persons)	10,200,000	18.1%

1. Based on 56,481,165 shares of our common stock issued and outstanding as of April 16, 2012.
2. Dr. Phillip Frost has sole voting and investment control over the securities held by Frost Gamma Investments Trust.
3. Mr. Prego-Novo, our sole officer and director, has sole voting and investment control over the securities held by Olyrcia Limited Partnership. Excludes 1,000,000 shares of common stock as to which Mr. Prego-Novo disclaims beneficial ownership.
4. Jane Hsiao, Ph.D. holds sole voting and investment control over the securities held by Aero Pharmaceuticals, Inc.
5. These shares are being held in escrow pending final determination of certain valuation calculations related to the BioZone Lab Group

### **Item 13. Certain Relationships and Related Transactions, and Director Independence.**

We manufacture our products in a 20,000 s.f. cGMP manufacturing and laboratory facility located at 580 Garcia Avenue, Pittsburg, CA, which we rent from 580 Garcia Properties, LLC, a related company which has been determined to be a variable interest entity and has been consolidated into the financial statements. Mr. Daniel Fisher, our former Executive Vice President, and his wife, Sharon Fisher, own all of the membership interests in 580 Garcia Properties, LLC. Related party rent for this facility for the year ended December 31, 2011 and 2010 was \$291,528 in each year, which amount has been eliminated in consolidation.

Phillip Frost, M.D., through Frost Gamma Investments Trust, beneficially owned approximately 46% of Aero's issued and outstanding capital stock, Roberto Prego-Novo, our Chairman, owned approximately 23% of Aero's issued and outstanding capital stock through Olyrca Trust. Each of Dr. Frost and Mr. Prego-Novo beneficially own approximately 5.35% and 3.70%, respectively (excluding, with respect to Mr. Prego-Novo, 1,000,000 shares of which he disclaims ownership), of our issued and outstanding capital stock following the Asset Purchase. Dr. Frost acquired his shares in February and March, 2011 for approximately \$0.027 per share and Mr. Prego-Novo acquired his shares in March 2011 for approximately \$0.03 per share. These prices were negotiated at arm's length when we had no viable business and prior to the acquisition of Aero and prior to a final letter of intent with Biozone Laboratories shareholders.

On February 28, 2012, the Company sold a \$100,000 note and issued warrants to purchase 500,000 shares of the Company's common stock to Robert Prego-Novo, Chairman of our Board of Directors.

Daniel Fisher, our former Executive Vice President and Director, advanced funds to the Company for working capital purposes in the aggregate amount of approximately \$1,099,715. The advances bear interest at a weighted average rate of approximately 10% and are due on demand. The Company is in dispute with Mr. Fisher as to the entire balance due but has recorded as a liability the full amount claimed by him.

### **Item 14. Principal Accountant Fees and Services.**

#### **Audit Fees**

The aggregate fees billed by our principal accountant for the audit of our annual financial statements, review of financial statements included in the quarterly reports and other fees that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for the years ended December 31, 2011 and 2010 was \$90,000 and \$187,000, respectively.

#### **Audit-Related Fees**

The aggregate fees billed by our principal accountant for assurance and advisory services that were related to the performance of the audit or review of our financial statements for the years ended December 31, 2011 and 2010 was \$25,000 and \$0, respectively.

#### **Tax Fees**

The aggregate fees billed for professional services rendered by our principal accountant for tax compliance, tax advice and tax planning for the fiscal years ended December 31, 2011 and 2010 was \$8,000 and \$0, respectively.

#### **Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors**

We do not currently have an Audit Committee. The policy of our Board of Directors, which acts as our Audit Committee, is to pre-approve all audit and permissible non-audit services provided by the independent auditors. These services may include audit services, audit-related services, tax services and other services. Pre-approval is generally provided for up to one year and any pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. The independent auditors and management are required to periodically report to our Board of Directors regarding the extent of services provided by the independent auditors in accordance with this pre-approval, and the fees for the services performed to date. The Board of Directors may also pre-approve particular services on a case-by-case basis.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules.

- 3.1 Articles of Incorporation (1)
- 3.2 Certificate of Amendment to Articles of Incorporation (1)
- 3.3 Certificate of Amendment to Articles of Incorporation (2)
- 3.4 Bylaws (1)
- 10.1 Asset Purchase Agreement, dated as of May 16, 2011, by and among the Company, Baker Cummins Corp. and Aero Pharmaceuticals, Inc.(4)
- 10.2 Assignment and Assumption Agreement, dated May 16, 2011, by and among the Company, Baker Cummins Corp. and Aero Pharmaceuticals, Inc. (4)
- 10.3 Bill of Sale, dated as of May 16, 2011, made and delivered by Aero Pharmaceuticals, Inc., to Baker Cummins Corp. (4)
- 10.4 Securities Purchase Agreement, dated as of February 28, 2011. (3)
- 10.5 Form of Secured Convertible Promissory Note (3)
- 10.6 Form of Warrant (3)
- 10.7 Form of Registration Rights Agreement (3)
- 10.8 Pledge and Security Agreement (3)
- 10.9 Non-Recourse Principal Stockholder Stock Pledge Agreement (3)
- 10.10 Director and Officer Indemnification Agreement (3)
- 10.11 Amendment No.1 to Asset Purchase Agreement dated as of April 25, 2011 by and between Aero Pharmaceuticals, Inc. and Teva Respiratory, LLC(4)
- 10.12 Form of LLC Membership Interest Purchase Agreement (Equalan LLC) (5)
- 10.13 Form of Stock Purchase Agreement (BioZone Laboratories Inc.) (5)
- 10.14 Form of LLC Membership Interest Purchase Agreement (Equachem LLC) (5)
- 10.15 Form of LLC Membership Interest Purchase Agreement (Betazone LLC) (5)
- 10.16 Form of Lockup Agreement (5)
- 10.17 Stock Option Agreement between Brian Keller and Opko Health, Inc. (5)
- 10.18 Stock Option Agreement between Daniel Fisher and Opko Health, Inc. (5)
- 10.19 Employment Agreement between the Company and Brian Keller (5)
- 10.20 Employment Agreement between the Company and Daniel Fisher (5)
- 10.21 Employment Agreement between the Company and Christian Oertle (5)
- 10.22 License Agreement (5)
- 10.23 Amendment No. 1 to License Agreement (5)

10.24	Amendment No. 2 to License Agreement (5)
10.25	Form of Securities Purchase Agreement (6)
10.26	Form of Convertible Promissory Note (6)
10.27	Form of Warrant (6)
10.28	Form of Registration Rights (6)
10.29	Form of Note Extension Agreement (7)
10.30	Form of Subscription Agreement (8)
10.31	Form of Subscription Agreement (9)
10.32	Form of Subscription Agreement (10)
10.33	Form of Warrant (10)
10.34	Form of Subscription Agreement (11)
10.35	Form of Warrant (11)
10.36	Form of Security and Stock Pledge Agreement (11)
10.37	Form of Note (12)
21	List of Subsidiaries(4)
31.1*	Section 302 Certification of Principal Executive Officer.
31.2*	Section 302 Certification of Principal Financial Officer.
32.1*	Section 906 Certification of Principal Executive Officer.
32.2*	Section 906 Certification of Principal Financial Officer.

\* Filed herewith

- (1) Incorporated by reference to the Company's Registration Statement on Form SB-2, filed with the SEC on September 20, 2007.
- (2) Incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed with the SEC on March 4, 2011.
- (3) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on March 1, 2011.
- (4) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on May 19, 2011.
- (5) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on July 7, 2011.
- (6) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on September 27, 2011
- (7) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on October 28, 2011
- (8) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on October 31, 2011
- (9) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on December 7, 2011
- (10) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on January 13, 2012
- (11) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on March 1, 2012
- (12) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on March 16, 2012

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### BIOZONE PHARMECEUTICALS, INC. (Registrant)

April 16, 2012

By: /s/ Elliot Maza  
Name: Elliot Maza  
Title: Chief Executive Officer and Chief Financial Officer  
(Principal Executive Officer and Principal Financial and Accounting Officer)

In accordance with the requirements of the Securities Act of 1933, this registration statement was signed by the following persons in the capacities and on the dates stated.

SIGNATURE

TITLE

DATE

/s/ Elliot Maza

Elliot Maza

Chief Executive Officer and Chief Financial Officer and Director

April 16, 2012

/s/ Roberto Prego-Novo

Roberto Prego-Novo

Chairman of the Board of Directors

April 16, 2012

/s/ Brian Keller

Brian Keller

President, Chief Scientific Officer and Director

April 16, 2012

**EXHIBIT 31.1**

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Elliot Maza, certify that:

- (1) I have reviewed this annual report on Form 10-K of Biozone Pharmaceuticals, Inc. for the fiscal year ended December 31, 2011;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 16, 2012

/s/ Elliot Maza

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Elliot Maza

Chief Executive Officer and Chief Financial Officer  
(Principal Executive Officer and Principal Financial and Accounting Officer)

**EXHIBIT 32.1**

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
PURSUANT TO 18 U.S. C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Biozone Pharmaceuticals, Inc., (the “Company”) on Form 10-K for year ended December 31, 2011 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Elliot Maza, Chief Executive Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 16, 2012

/s/ Elliot Maza

Elliot Maza

Chief Executive Officer and Chief Financial Officer

(Principal Executive Officer and Principal Financial and Accounting Officer)