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

Amendment No. 8 to

## Form S-1

# REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

# BIOZONE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

| Nevada  | 7389   | 20-5978559   |
|---|--|--|
| (State or other jurisdiction  | (Primary Standard Industrial                 | (I.R.S. Employer   |
| of incorporation or organization)   | Classification Code Number)                  | Identification Number)   |
| (Address, including zip code, and telep   | phone number, including area code, of reg    | ristrant's principal executive offices)  |
|   | Elliot Maza                                  |  |
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| Approximate date of commencement of propostatement.   | sed sale to the public: As soon as practic   | cable after the effective date of this registration  |
| If any of the securities being registered on to Securities Act of 1933, check the following box.                                |  | continuous basis pursuant to Rule 415 under the  |
| If this Form is filed to register additional se following box and list the Securities Act of 1933 offering. $\Box$              |  | 162(b) under the Securities Act, please check the lier effective registration statement for the same   |
| If this Form is a post-effective amendment is Securities Act registration statement number of the                               |  | curities Act, check the following box and list the r the same offering.                                |
| If this Form is a post-effective amendment of Securities Act registration statement number of the                               |  | curities Act, check the following box and list the r the same offering.                                |
| Indicate by a check mark whether the regis<br>reporting company. See the definitions of "large at<br>Exchange Act. (Check One): |  | erated filer, a non-accelerated filer, or a smaller<br>smaller reporting company" in Rule 12b-2 of the |
| Large Accelerated Filer □   |  | Accelerated Filer □  |
| Non-Accelerated Filer □ (Do not check if a small  | er reporting company)                        | Smaller Reporting Company  |
| Exchange Act. (Check One):  Large Accelerated Filer □   | ler reporting company)                       | Accelerated Filer  Smaller Reporting Compa   |

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

## **SUBJECT TO COMPLETION, DATED FEBRUARY 13, 2013**

#### PRELIMINARY PROSPECTUS

#### 8,345,310 Shares

## BIOZONE PHARMACEUTICALS, INC.

#### **Common Stock**

This prospectus relates to the sale by the selling stockholder identified in this prospectus of up to 8,345,310 shares of our common stock. All of these shares of our common stock are being offered for resale by the selling stockholder.

The prices at which the selling stockholder may sell shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any proceeds from the sale of these shares by the selling stockholder.

We will bear all costs relating to the registration of these shares of our common stock, other than any selling stockholder's legal or accounting costs or commissions.

Our common stock is quoted on the Over-the-Counter Bulletin Board under the symbol "BZNE.OB". The last reported sale price of our common stock as reported by the OTC Bulletin Board on February 12, 2013, was \$ 3.75 per share.

Investing in our common stock is highly speculative and involves a high degree of risk. You should carefully consider the risks and uncertainties described under the heading "Risk Factors" beginning on page 3 of this prospectus before making a decision to purchase our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 13, 2013

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You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where an offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

#### PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. This summary may not contain all of the information that may be important to you. You should read this entire prospectus carefully, including the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our historical financial statements and related notes included elsewhere in this prospectus. In this prospectus, unless the context provides otherwise, the terms "the Company," "we," "us," and "our" refer to BioZone Pharmaceuticals, Inc.

#### Overview

We are a manufacturer of health, beauty and drug products. We operate through BioZone Pharmaceuticals, Inc. ("BioZone Pharma") and its four wholly owned subsidiaries: BioZone Laboratories, Inc. ("BioZone Labs"), Equalan LLC ("Equalan"), Equachem LLC ("Equachem") and Baker Cummins Corp. ("Baker Cummins").

Our manufacturing business consists of the development and manufacture of over-the-counter (OTC) pharmaceuticals, and skin care, cosmetic and beauty products for third party contract manufacturing customers. We utilize certain proprietary drug delivery technology in the topical and liquid products that we manufacture for third parties, which we refer to as QuSomes ® . We do not rely on any third parties to manufacture our products.

Our contract manufacturing customers are regional and national distributors and retailers of healthcare products. Our core business strategy for our manufacturing business is to leverage our QuSomes technology as a value added enhancement.

We manufacture and sell two proprietary brands of skin care products: Glyderm @ and Baker Cummins @. Our Glyderm and Baker Cummins customers are drug wholesalers, physicians who use and resell our products in their physician practices and customers who purchase our products over the internet.

In addition, we sell pharmaceutical ingredients containing QuSomes to various healthcare supply manufacturers. Also, we are conducting research related to potential improvements in certain excipients commonly used in generic pharmaceutical products using our proprietary drug delivery technology, which we refer to as EquaSomes TM . Our research activities are an immaterial portion of our overall business and are described in greater detail in our business section below.

We conduct our manufacturing business and research activities through BioZone Labs, our proprietary brand business through Equalan and Baker Cummins and our pharmaceutical ingredient distribution business through Equachem. Equalan markets the Glyderm brand of skin care products, which can be used to improve skin texture and tone. Baker Cummins markets the "P&S" line of scalp and skin care products, which can be used to treat common skin and scalp conditions. These products are sold OTC and include liquids and lotions.

We have licensed the use of QuSomes to BetaZone Pharmaceuticals, LLC ("BetaZone), our 45% owned subsidiary, for application in certain products marketed and to be marketed in Mexico, Central America and South America and for application in certain products marketed outside of countries in those regions.

On February 24, 2012, BioZone Pharma, BioZone Labs, and Equachem (the "BZL Licensors") and OPKO Pharmaceuticals, LLC ("OPKO") entered into a Limited License Agreement pursuant to which OPKO acquired an exclusive license to the QuSomes and EquaSomes drug delivery technology for use in ophthalmological indications and a non-exclusive license to such technology for all other indications.

QuSomes ® , Glyderm ® , Baker Cummins ® and EquaSomes TM are trademarks that we own.

## **Our History**

We were incorporated under the laws of the State of Nevada on December 4, 2006. On March 1, 2011, we filed a Certificate of Amendment to our Articles of Incorporation in order to change our name to BioZone Pharmaceuticals, Inc. from International Surf Resorts, Inc. Prior to March 2011, we were generally seeking to engage in the business of operating an internet provider of international surf resorts, camps and guided surf tours. In December 2011, we transferred our 55% ownership in ISR de Mexico, S. R.L. de C. V., a Mexican corporation, to certain of our former shareholders in return for and cancellation of 13,948,001 shares of our common stock.

On May 16, 2011, we acquired the assets and assumed the liabilities of Aero Pharmaceuticals, Inc. ("Aero") a Florida corporation, pursuant to an asset purchase agreement dated as of May 16, 2011 by and between the Company, Baker Cummins, and Aero. The asset purchase agreement constituted a plan of reorganization within the meaning of Treasury Regulations Section 1.368-2(g) and constituted a plan of liquidation of Aero. As a result of the asset purchase, we acquired the business of Aero consisting of the manufacturing, marketing and distribution of dermatological products under the trade name of Baker Cummins Dermatologicals (collectively, the "Baker Cummins Assets"). In exchange for the asset purchase we issued an aggregate of 8,331,396 shares of our restricted common stock to Aero, which are being registered hereunder. The transaction was intended to be tax-free for federal income tax purposes, as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "Code"), and the regulations promulgated thereunder. On September 21, 2011, we issued an additional 13,914 shares to Aero due to the late filing of this registration statement, which shares are also registered hereunder. On December 11, 2011, Aero transferred the shares to the Aero Liquidity Trust, which holds the shares for the benefit of the holders of Aero's common stock.

Under the asset purchase agreement with Aero, we acquired the following products, marketed under the Baker Cummins brand: P&S Liquid, P&S Shampoo, Ultra Mide 25 Lotion, Ultra Mide-D, X-Seb T Pearl Shampoo, X-Seb T Plus Shampoo, and Acquaderm Cream.

Under the asset purchase agreement with Aero, we purchased (i) all rights to manufacture, distribute, market and sell the Baker Cummins Assets, (ii) all trademarks, marketing materials, training materials, market data, clinical data, research data, regulatory data, adverse event data, trade dress information and product labeling data associated with the Baker Cummins assets, (iii) all outstanding customer purchase orders for the Baker Cummins assets, (iv) all contracts relating to the Baker Cummins Assets, (v) all of Aero's existing inventory of the Baker Cummins Assets, (vi) all cash and cash equivalents, (vii) all accounts or notes receivable held by Aero, (viii) all furniture, fixtures, equipment and machinery, books and records related to the Baker Cummins Assets, (ix) all technological, scientific, chemical, biological, pharmaceutical, toxicological, regulatory and clinical trial materials and information relating to the Baker Cummins Assets, and (x) all information owned or licensed by Aero relating to specifications and test methods, raw materials, packaging instructions, master formulas, validation reports, stability data, analytical methods, records of complaints, annual product reviews and other master documents necessary for the manufacture, control and release of the Baker Cummins Assets.

On June 30, 2011, we entered into stock purchase agreements with the shareholders of BioZone Labs pursuant to which we purchased 100% of the outstanding common stock of BioZone Labs. Also on that date, we entered into LLC Membership Interest Purchase Agreements with the members of Equalan and Equachem, pursuant to which we purchased 100% of the outstanding membership interests of Equalan and Equachem, and LLC Membership Interest Purchase Agreements with certain members of BetaZone pursuant to which we purchased 45% of the outstanding membership interests of BetaZone. Under the terms of the foregoing agreements, we issued an aggregate of 21,000,000 shares of our common stock to the owners of the BioZone Labs, subject to the terms of an escrow agreement dated as of June 30, 2011.

#### THE OFFERING

Common stock offered by selling stockholder: This prospectus relates to the sale by a single selling stockholder of

8,345,310 shares of our restricted common stock, issued pursuant to an Asset Purchase Agreement dated as of May 16, 2011 by and among the Company,

Baker Cummins Corp. and Aero Pharmaceuticals, Inc.

Offering price: Market price or privately negotiated prices.

Common stock outstanding before and after the

offering:

63,142,969 (1)

Use of proceeds: We will not receive any proceeds from the sale of the common stock by the

selling stockholder.

OTC Symbol: BZNE.OB

Risk Factors: You should carefully consider the information set forth in this prospectus and, in

particular, the specific factors set forth in the "Risk Factors" section beginning on page 3 of this prospectus before deciding whether or not to invest in our common

stock

(1) Represents the number of shares of our common stock issued and outstanding as of February 12, 2013.

## SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This prospectus 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 prospectus 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.

## RISK FACTORS

Investing in our common stock involves a high degree of risk. Prospective investors should carefully consider the risks described below, together with all of the other information included or referred to in this prospectus, before purchasing shares of our common stock. There are numerous and varied risks as set forth below that may prevent us from achieving our goals. If any of these risks actually occur, our business, financial condition or results of operations may be materially adversely affected. In such case, the trading price of our common stock could decline and investors 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 a net loss of \$4,459,204 for the nine months ended September 30, 2012 and net losses of \$5,457,310 and \$319,813 for the years ended December 31, 2011 and 2010, respectively 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 and allow us to continue 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 and have sustained operating losses during the past several years.

As of September 30, 2012, we had negative working capital of \$ 1,777,778 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. We have sustained losses for the years ended December 31, 2010 and 2011.

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 years ended December 31, 2011 and 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 prospectus, 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 prescription 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 to us 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 and in August 2012, the FDA performed three separate GMP surveillance inspections of BioZone Labs' facilities located in Pittsburg, California to audit our compliance against 21CFR Part 210 and Part 211, cGMP. The 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's 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 three 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.

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 as part of our sales price to them. 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 upon 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 provisions in our employee handbook and individual consulting agreements 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. Our employee handbook, a copy of which is signed by each employee, provides that employees shall not disclose any of our trade secrets, directly or indirectly, or use them in any way, either during the term of their employment or at any time thereafter, except as required in the course of employment with the Company. However, the confidentiality provisions in our employee handbook and consulting agreements may be breached and in addition, 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 their 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, our Chief Executive Officer, Chief Financial Officer and Secretary; 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. Dr. Keller and Mr. Oertle are each subject to three year written employment agreements with the Company. 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. We are competing for employees against companies that are more established than we are, and have the ability to pay more cash compensation than we do. As of the date hereof, we have not experienced problems hiring employees in the recent past.

## 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 10,639,467 shares of the Company's common stock, which represents approximately 16. 3 % of our issued and outstanding common stock as of February 12, 2013. Therefore, our officers and directors could exert substantial influence over any 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.OB. 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.

In addition, the value of our common stock could be affected by actual or anticipated variations in our operating results; 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.

Stockholders may experience wide fluctuations in the market price of our securities. These fluctuations may have an extremely negative effect on the market price of our securities and 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 market price which is lower than the purchase price the stockholder paid, or to hold our securities for a longer period of time than planned. An inactive market may also impair our ability to raise capital by selling shares of capital stock and may impair our ability to acquire other companies by using common stock as consideration or to recruit and retain managers with equity-based incentive plans.

## We cannot assure you that our common stock will become listed on NYSE MKT LLC, Nasdaq or any other securities exchange.

We plan to seek listing of our common stock on NYSE MKT LLC 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 do not meet the corporate governance standards of either Nasdaq or NYSE MKT LLC as they relate to director independence and the formation of an independent audit and compensation committee of our Board of Directors. We do not currently have an audit committee or a compensation committee of our Board of Directors nor do we currently have any independent members of our Board of Directors. Until our common stock is listed on NYSE MKT LLC 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.

# Our common stock may be affected by limited trading volume and price fluctuation which could adversely impact the value of our common stock.

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. Our common stock has experienced, and is likely to experience in the future, significant price and volume fluctuations which could adversely affect the market price of our common stock without regard to our operating performance. 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 also 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, therefore, can offer no assurances that the market for our common stock will be stable or appreciate over time.

#### 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.

#### **USE OF PROCEEDS**

The selling stockholder will receive all of the proceeds from the sale of the shares offered by them under this prospectus. We will not receive any proceeds from the sale of the shares by the selling stockholder covered by this prospectus.

## MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

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 February 12, 2013, there were approximately 92 holders of record of our common stock.

| H  | ligh           |  | Low  |
|----|----------------|--|--|
| \$ | 5.50           | \$                                       | 1.50   |
| \$ | 4.65           | \$                                       | 1.50   |
| \$ | 4.64           | \$                                       | 3.68   |
|    |                |  |  |
|    |                |  |  |
| \$ | 3.69           | \$                                       | 1.60   |
| \$ | 4.00           | \$                                       | 1.04   |
| \$ | 4.00           | \$                                       | 0.51   |
|    | \$<br>\$<br>\$ | \$ 4.65<br>\$ 4.64<br>\$ 3.69<br>\$ 4.00 | \$ 5.50 \$ \$ 4.65 \$ \$ 4.64 \$ \$ \$ \$ 4.64 \$ \$ \$ \$ \$ 4.00 \$ \$ |

3.46

0.51

The last reported sales price of our Common stock on the OTC Bulletin Board on February 12, 2013 was \$3.75 per share.

October 1, 2012 through December 31, 2012

#### 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.

#### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this prospectus. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under "Risk Factors".

The following discussion and analysis should be read in conjunction with our unaudited consolidated financial statements and related notes included in this report. This report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The statements contained in this report that are not historic in nature, particularly those that utilize terminology such as "may," "will," "should," "expects," "anticipates," "estimates," "believes," or "plans" or comparable terminology are forward-looking statements based on current expectations and assumptions. Various risks and uncertainties could cause actual results to differ materially from those expressed in forward-looking statements.

The safe harbor for forward-looking statements provided by Section 21E of the Securities Exchange Act of 1934 excludes issuers of "penny stock" (as defined under Rule 3a51-1 of the Securities Exchange Act of 1934). Our common stock currently falls within that definition.

All forward-looking statements in this document are based on information currently available to us as of the date of this report, and we assume no obligation to update any forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements.

#### Overview

BioZone Pharmaceuticals, Inc. (formerly, International Surf resorts, Inc.) was incorporated under the laws of the State of Nevada on December 4, 2006.

On May 16, 2011, the Company acquired substantially all of the assets and assumed all of the liabilities of 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 of Baker Cummins Dermatologicals.

On June 30, 2011, the Company acquired the BioZone Lab Group, which operates 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. In addition, we have been developing our proprietary drug delivery technology as an enhancement for approved, generic prescription drugs that are limited due to poor stability or bioavailability or variable absorption.

### **Results of Operations**

#### Three Months Ended September 30, 2012 Compared to the Three Months Ended September 30, 2011:

#### Sales.

Sales for the three months ended September 30, 2012 and 2011 were \$4,893,758 and \$3,930,503, respectively. The increase in sales of \$963,255 or 24.5% was primarily attributable to increases in customer orders from increased end-user demand.

## Cost of Sales and Gross Profit.

Cost of sales for the three months ended September 30, 2012 and 2011 was \$2,871,266 and \$1,845,127, respectively, resulting in gross profit of \$2,022,492 and \$2,085,376, respectively. The gross profit percentage for the three months ended September 30, 2012 and 2011 was approximately 41% and 53%, respectively. The decrease in gross profit of \$62,884 and resulting decrease in gross profit percentage is largely attributable to an increase in raw material costs.

## Operating Expenses.

We had total operating expenses of \$1,660,174 for the three months ended September 30, 2012 as compared to \$4,301,668 for the three months ended September 30, 2011. The decrease in operating expenses of \$2,641,494 or 61.4% is due to a decrease in general and administrative expenses of \$2,711,718 which is primarily due to stock based compensation of \$1,950,000 which was recorded in the quarter ended September 30, 2011, while the remainder of the decrease in general and administrative expenses is due primarily to a decrease in professional fees of \$555,000, which were incurred as the Company was getting started in the prior year period. Our selling expenses decreased by \$81,706 or 38.4% to \$131,085 for the three months ended September 30, 2012 from \$212,791 for the three months ended September 30, 2011, as we have worked to streamline our sales operations across our product lines. Our research and development expenses increased \$151,930, which primarily is due to the opening of our research facility in Princeton, New Jersey and the addition of five new staff members.

# Interest Expense.

We incurred interest expense of \$482,960 for the three months ended September 30, 2012 as compared to \$283,411 for the three months ended September 30, 2011. The increase in interest expense of \$199,549 is primarily due to larger average outstanding debt in the current year quarter compared to the prior year quarter.

#### Change in value of derivative instruments.

We recorded a gain of \$21,912 for the three month period ended September 30, 2012 resulting from the decrease in the fair value of our derivative instruments. We had no derivative instruments outstanding with measurable fair value during the comparable period last year.

#### Net Loss / Income.

As a result of the foregoing, we realized a net loss of \$98,730 for the three months ended September 30, 2012 as compared to a net loss of \$2,499,703 for the three months ended September 30, 2011, a decrease in net loss of \$2,400,973.

### Nine Months Ended September 30, 2012 Compared to the Nine Months Ended September 30, 2011:

#### Sales.

Sales for the nine months ended September 30, 2012 and 2011 were \$13,315,944 and \$8,937,818 respectively. The increase in sales of \$4,378,126 or 49.0% was primarily attributable to increases in customer orders from increased end-user demand for our products.

#### Cost of Sales and Gross Profit.

Cost of sales for the nine months ended September 30, 2012 and 2011 were \$7,817,619 and \$5,209,891, respectively, resulting in gross profit of \$5,498,325 and \$3,727,927, respectively. The gross profit percentage for the nine months ended September 30, 2012 and 2011 was approximately 41% and 42%, respectively. The increase in gross profit of \$1,770,398 is largely attributable to an increase in customer orders from increased end-user demand for our products.

#### Operating Expenses.

We had total operating expenses of \$5,464,702 for the nine months ended September 30, 2012 as compared to \$6,833,633 for the nine months ended September 30, 2011. The decrease in operating expenses of \$1,368,931 or 20.0% is due to a decrease of general and administrative expenses of \$1,931,507, which primarily is due to an decrease in stock based compensation of \$1,950,000, partially offset by small increases in other accounts. Our selling expenses increased by \$97,684 or 19.6% to 595,622 for the nine months ended September 30, 2012, compared to \$497,938 for the nine months ended September 30, 2011, due to the sales increase. Our research and development expenses increased \$464,892, which primarily is due to the opening of our research facility in Princeton, New Jersey and the addition of five new staff members.

#### Interest Expense.

We incurred interest expense of \$4,970,657 for the nine months ended September 30, 2012 as compared to \$505,606 for the nine months ended September 30, 2011. The increase in interest expense of \$4,465,051 is due to the recording of a debt discount of \$3,692,528 related to the derivative liability of the warrants issued in connection with the convertible notes issued in 2012, accretion of debt discount of \$383,333 and interest payments related to the repayment of the March 2011 Notes as well as larger average outstanding balances.

## Change in value of derivative instruments.

We recorded a gain of \$477,830 for the nine month period ended September 30, 2012 on the fair value of our derivative instruments. We had no derivative instruments outstanding with measurable fair value during the comparable period last year.

## Net Loss / Income.

As a result of the foregoing, we realized a net loss of \$4,459,204 for the nine months ended September 30, 2012 as compared to a net loss of \$3,611,312 for the nine months ended September 30, 2011, an increase in net loss of \$847,892.

#### **Liquidity and Capital Resources**

As of September 30, 2012, our current assets were \$3,643,566, as compared to \$2,904,436 at December 31, 2011. As of September 30, 2012, our current liabilities were \$5,421,344, as compared to \$7,278,170 at December 31, 2011. The Company's operating activities used net cash of \$1,636,699 for the period ended September 30, 2012, as compared to using net cash of \$40,986 for the period ended September 30, 2011.

During the period ended September 30, 2012, investing activities used net cash of \$320,116, comprised of cash used for the purchase of property and equipment. During the period ended September 30, 2011, investing activities provided cash of \$428,152, primarily cash acquired in the Aero acquisition.

During the period ended September 30, 2012, cash of \$1,623,103 was provided by financing activities, consisting of proceeds from the issuance of convertible notes of \$3,750,000, and the sale of common stock of \$650,000. This was offset by repayment of convertible notes payable of \$2,550,000, repayments of debt of \$190,593, and the payment of financing costs of \$36,304, as compared to net cash provided by financing activities of \$143,084 during the nine-month period ended September 30, 2011, which consisted of proceeds from convertible notes of \$2,750,000, offset by repayments of existing debt of \$2,453,341, the payment of financing costs of \$150,364, and payment to shareholder of \$3,211.

Our net loss for the nine months ended September 30, 2012 and 2011 was a loss of \$4,459,204 and a loss of \$3,611,312, respectively. The increase in net loss of \$847,892 includes the effect of non-cash expenses of \$4,627,986 offset by a non-cash gain of \$477,830 related to the issuance of convertible notes and warrants. As of September 30, 2012, we had cash and cash equivalents of \$82,621 and negative working capital of \$1,777,778, which includes a non-cash derivative liability of \$595,104.

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.

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. As of September 30, 2012 we have a shareholder deficiency of \$74,927, negative working capital of \$1,777,778 (which includes a non-cash derivative liability of \$595,104), and have sustained operating losses for the prior two fiscal years. These conditions, among others, 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.

In view of these matters, realization of a major portion of the assets in the accompanying balance sheet is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financing requirements, and the success of its future operations. Management believes that actions presently being taken to revise the Company's operating and financial requirements provide the opportunity for the Company to continue as a going concern.

#### Off-Balance Sheet Arrangements

As of September 30, 2012 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 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).

On January 30, 2012, Mr. Fisher was removed from his position as Executive Vice President for cause as provided for in Mr. Fisher's employment Agreement. On February 3, 2012, Mr. Fisher resigned from our Board of Directors. Pursuant to Mr. Fisher's employment agreement, Mr. Fisher is entitled to accrued salary through the date of termination. As of the date of filing of this Amendment to the Registration Statement, we have paid Mr. Fisher a total of \$49,712. The remaining amount due is \$6,133.

The Company believes that in connection with the audit performed following closing, various material misrepresentations were revealed in the unaudited presentation of the financial condition, assets and liabilities of BioZone for the year ended December 31, 2010, including overstatements of 2010 gross income by \$1 million and 2010 year-end inventory by approximately \$800,000. These overstatements were corrected on audit and did not affect the historical financial statements filed with the SEC on Form 8K/A. The Company has asserted rights under the escrow agreement that required a post-closing audit and under the employment agreements. Mr. Fisher has asserted certain claims against the Company, and on July 16, 2012, Mr. Fisher commenced an action in the United States District Court in the Northern District of California alleging certain causes of action against the Company, which are further described in the section entitled "Legal Proceedings" herein. On July 18, 2012, the Company commenced an action in the New York State Court against Fisher alleging, among other things, breach of contract, breach of fiduciary duty and negligence. Further discussion of these proceedings is described in the section entitled "Legal Proceedings" herein. The Company believes it has the right to terminate Mr. Fisher and void any share issuances, although the outcome of any future litigation or dispute cannot be predicted.

#### 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 square feet, cGMP facility in Pittsburg, California owned by 580 Garcia Avenue, LLC, its consolidated VIE, and fills and stores its products at a 60,000 square feet 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. We employ two sales professionals for our Baker Cummins brand proprietary skin care products, both of whom are located in Miami, Florida. The lease expires on October 31, 2012 and provides for annual rentals of approximately \$26,472. Our rent expense for our Miami facility through the end of the lease is \$2,282.

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 2,000 square feet of office space. The lease expires on June 30, 2013. Rent expense is approximately \$2,250 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.

## 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, Miami, Florida and Englewood Cliffs, New Jersey.

BioZone Labs manufactures its products in a 20,000 square feet, cGMP facility located at 580 Garcia Avenue, Pittsburg, CA 94565 owned by 580 Garcia Avenue, LLC, its consolidated VIE, and packs, fills, labels and stores its products at a 60,000 square foot rented facility located at 701 Willow Pass Road, Pittsburg, CA. The lease for the 580 Garcia Avenue facility expires in February 2029 and provides for monthly rental payments equal to all amounts due to the mortgage lender plus an additional monthly amount of \$3500. The lease for the Willow Pass Road facility expires in July 2014 and provides for monthly rentals of approximately \$28,610.

The Company believes Mr. Fisher directly or indirectly owns 580 Garcia Avenue, LLC. The 580 Garcia Avenue facility is encumbered by mortgage debt of approximately \$2.6 million. BioZone Labs pays approximately \$21,000 per month directly to the mortgage lender, which it treats as rent paid to 580 Garcia Avenue, LLC. The Company believes the property to be worth approximately \$800,000, and that the lease payments for the 580 Garcia Avenue facility are substantially above the market price for similar facilities. In addition, Mr. Fisher claims the Company is indebted to 580 Garcia Avenue, LLC for loans in the aggregate principal amount of approximately \$1.1 million, which Mr. Fisher claims are in default.

We lease approximately 1,500 square feet of office space at 4400 Biscayne Boulevard, Miami, Florida. We employ one sales professionals for our Baker Cummins brand proprietary skin care products, both of whom are located in Miami, Florida. The lease expired on October 31, 2012 and provided for monthly rentals of approximately \$2,000. We are negotiating a new lease for reduced space.

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. In September 2012, the Company terminated research and development activities at this location, including personnel connected with such efforts and the Company's former consultant, Nian Wu, agreed to use his best efforts to assume such lease pursuant to the terms of his Separation Agreement.

Our corporate headquarters is located at 550 Sylvan Avenue, Englewood Cliffs, New Jersey, where we lease approximately 1,250 square feet of office space. The lease expires on June 30, 2013. Rent expense is approximately \$2,250 per month.

#### Seasonality

Certain 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 the Company and its subsidiaries, all of which are wholly owned, its equity investment in Betazone, Inc. and 580 Garcia Ave, LLC ("580 Garcia") a Variable Interest Entity ("VIE").

The Company considered the terms of its interest in 580 Garcia and determined that 580 Garcia is a VIE in accordance with ACS 810-10-55, which should be consolidated. As of September 30, 2012, amounts included in the consolidated assets relating to 580 Garcia, which are shown in property and equipment, and consolidated liabilities, which are reported in long-term debt, total \$766,205 and \$2,613,675, respectively. The Company's involvement with the entity is limited to its lease to rent the facility from 580 Garcia, with the Company as the only tenant, and the guarantee of the mortgage loan on the property of 580 Garcia. The Company's maximum exposure to loss, based on the Company's guarantee of the mortgage loan of 580 Garcia, is \$2,613,675, which equals the carrying amount of the liability as of September 30, 2012.

Our investment in Betazone, which is our significant unconsolidated subsidiary, is accounted for using the equity method of accounting.

### Revenue Recognition

BioZone Labs operates as a contract manufacturer and produces finished goods according to customer specifications. Equalan sells its merchandise directly to dermatologists, wholesalers, online retailers and consumers. Equachem operates as a reseller of pharmaceutical raw materials. 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, which is comprised of sales based royalties received from our licensee, is recorded when reported to us by the licensee. We are entitled to a royalty equal to a percentage of net sales by our licensee of products covered by valid patents that we own. Royalties are paid to us on a quarterly basis for sales occurring within that quarter as reported to us by the licensee within 30 days following the end of each quarter.

#### 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.

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.

## **BUSINESS**

#### Overview

Biozone Pharma, through its wholly owned subsidiary, BioZone Labs, is primarily engaged in the business of developing and manufacturing OTC drug products and skin care, cosmetic and beauty products on behalf of third parties. In addition, through its wholly owned subsidiaries, Equalan and 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, 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. The sales by Equachem and, 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. The 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 skin care, 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.

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 \$400,000 per year and do not constitute a material component of our business.

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, California. We fill, package, label and store these products at a 60,000 sq. ft. packaging and warehouse facility located at 701 Willow Pass Road, Pittsburg, California. 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.

In January and November 2011 and August 2012, the FDA performed three separate GMP surveillance inspections of BioZone Labs' manufacturing facility and warehouse facilities in order to audit our compliance against 21CFR Part 210 and Part 211, Good Manufacturing Practices with respect to our OTC drug product manufacturing procedures. All three 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, our procedures for handling deviations from test procedures, standards for rejecting drug products failing to meet established specifications, maintenance of electronic records, accessibility of written records, and preparation of analytical laboratory 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. We expect to complete the remediation process by March 2013.

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.

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.

*Skin Care, 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:

| Product Name  | Indication or Target Market  |
|---|--|
| Glycolic Acid Peels – 20% to 70%  | Health care practioners for in office use to improve the texture and tone of<br>the skin and clean out pores and help even out pigmentation and give the<br>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 sixweek 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 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:

| Product Name                                   | Indication or Target Market   |  |
|--|---|--|
| P&S Liquid                                     | Treatment for symptoms of psoriasis and seborrhea dermatitis by hel 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 Pittsburg, California, 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. We have licensed the use of the QuSome technology to BetaZone, our 45% owned subsidiary, for application in certain products marketed and to be marketed in Mexico, Central America and South America, and for application in certain products marketed outside of countries in those regions. BetaZone has yet to pay us any material royalties as it has yet to generate any significant sales or license payments from products using our licensed technology

On February 24, 2012, BioZone Pharma, BioZone Labs, and Equachem (the "BZL Licensors") and OPKO Pharmaceuticals, LLC ("OPKO") entered into a Limited License Agreement pursuant to which OPKO acquired an exclusive license to the QuoSomes and EquaSomes TM drug delivery technology for use in ophthalmological indications and a non-exclusive license to such technology for all other indications. Pursuant to the Limited License Agreement, the Company shall pay 5% of Net Sales (as defined in the Limited License Agreement) of the Covered Products (as defined in the Limited License Agreement) to the BZL Licensors. The royalty term shall terminate on a country-by-country basis on the first date that such Covered Product ceases to be covered by a Valid Claim (as defined in the Limited License Agreement) in a country. Unless otherwise terminated, the Limited License Agreement shall remain in effect until the expiration of the last-to-expire patent within the BZL Patents (as defined in the Limited License Agreement). The BZL Licensors may terminate the license granted under the Limited License Agreement for cause upon written notice to OPKO and OPKO may terminate any licence granted to it by providing 90 days written notice to the BZL Licensors.

## **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.

Recently, we developed a pegylated lipid, which we refer to as EquaSomes TM, for use in combination with drugs administered by injection or infusion. We have yet to perform any human clinical studies with respect to any product candidate. Total research and development costs for the fiscal years ended December 31, 2011 and 2010 were \$399,624 and \$240,873, respectively.

In March 2011, we established a small scale research and lipid manufacturing facility in Princeton, New Jersey, to advance our efforts to formulate certain generic drug products with a combination of an active pharmaceutical ingredient and EquaSomes. In September 2012, we terminated research and development activities at this location, including personnel connected with such efforts and our former consultant. Dr. Nian Wu, a former consultant to the Company, agreed to use his best efforts to assume the lease of the facility pursuant to the terms of his Separation Agreement.

# **Intellectual Property**

The following table lists all patents and patent applications 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.

| Patent Title   | Patent or Application Number | Filing or Effective Date |
|--|------------------------------|--------------------------|
| Delivery of biologically active material in a liposomal    | 5891465                      | April, 1999              |
| formulation for administration into the mouth              |                              |                          |
| Liposomal delivery by iontophoresis                        | 6048545                      | April, 2000              |
| Compounds and methods for inhibition of phospholipase A2   | 6495596                      | December, 2002           |
| and cyclooxygenase-2                                       |                              |                          |
| Self-forming, thermodynamically stable liposomes and their | 6610322                      | August, 2003             |
| applications   |                              |                          |
| Oral Liposomal Delivery System                             | 6776924                      | April, 2004              |
| Self-forming, thermodynamically stable liposomes and their | 6958160                      | October, 2005            |
| applications   |                              |                          |
| Compounds and methods for inhibition of phospholipase A2   | 6998421                      | February, 2006           |
| and cyclooxygenase-2                                       |                              |                          |
| Self-forming, thermodynamically stable liposomes and their | 7150883                      | December, 2006           |
| applications   |                              |                          |
| Self-forming, thermodynamically stable liposomes and their | 7718190                      | May, 2010                |
| applications   |                              |                          |
| Self-forming, thermodynamically stable liposomes and their | 4497765                      | April, 2010              |
| applications - Japan                                       |                              |                          |
| X-conazoles plus Qusomes                                   |                              |                          |
| EQUA-001 (regular application) "Enhanced Delivery of       | 12/006,820                   | January, 2008            |
| Antifungal Agents"   |                              |                          |
| 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                |
| Pure PEG-Lipid Conjugates                                  |                              |                          |
| 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               |
| Cyclosporin formulation                                    |                              |                          |
| EQUA-016P  | 61/273,656                   | August, 2009             |
| EQUA-025R  | 12/802,200                   | June, 2010               |
| EQUA-025 PCT   | PCT/US2010/001589            | June, 2010               |
| Rapamycin  |                              |                          |
| 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             | PCT/US2010/002547            | September, 2010          |
| Rapamycin"   |                              |                          |

## **Customers and Marketing**

BioZone Labs sells products to more than 50 customers through sales professionals who market development, formulation and manufacturing services to potential customers. During the three months ended September 30, 2012, Matrixx Initiatives, Inc. and Savvier LP accounted for approximately 3 7 % and 2 1 % of the Company's sales. During the year ended December 31, 2011, four customers accounted for approximately 30%, 9%, 8% and 7% of the Company's sales. If any of these 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.

Generally, we satisfy customer orders on an individual purchase order basis and do not enter into manufacturing agreements. We have a manufacturing agreement with our largest customer, which provides, among other things, that we will be the exclusive manufacturer of the products described in the agreement for a specified term; the pricing for our manufacturing services, which is subject to change during the term, and provides for payment and allowances. The agreement has a three year term and provides for annual renewals. The agreement does not require the customer 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 QuSome technology and 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, including 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.

The market for OTC health care products is highly competitive and promotion sensitive. Our direct competition consists of numerous drug manufacturers and marketers, many of which have greater financial and other resources than we do. If one or more other pharmaceutical manufacturers significantly reduce their prices or significantly increase their promotional activity in an effort to gain market share, our gross revenue from sales of proprietary health care products, 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 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.

### 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 80% to 85% of our revenue is generated in the first three quarters of the calendar year.

## **Properties**

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

BioZone Labs manufactures its products in a 20,000 square feet, cGMP facility located at 580 Garcia Avenue, Pittsburg, CA 94565 owned by 580 Garcia Avenue, LLC, its consolidated VIE, and packs, fills, labels and stores its products at a 60,000 square foot rented facility located at 701 Willow Pass Road, Pittsburg, CA. The lease for the 580 Garcia Avenue facility expires in February 2029 and provides for monthly rental payments equal to all amounts due to the mortgage lender plus an additional monthly amount of \$3500. The lease for the Willow Pass Road facility expires in July 2014 and provides for monthly rentals of approximately \$28,610.

The Company believes Mr. Fisher directly or indirectly owns 580 Garcia Avenue, LLC. The 580 Garcia Avenue facility is encumbered by mortgage debt of approximately \$2.6 million. BioZone Labs pays approximately \$21,000 per month directly to the mortgage lender, which it treats as rent paid to 580 Garcia Avenue, LLC. The Company believes the property to be worth approximately \$800,000, and that the lease payments for the 580 Garcia Avenue facility are substantially above the market price for similar facilities. In addition, Mr. Fisher claims the Company is indebted to 580 Garcia Avenue, LLC for loans in the aggregate principal amount of approximately \$1.1 million, which Mr. Fisher claims are in default.

We lease approximately 1,500 square feet of office space at 4400 Biscayne Boulevard, Miami, Florida. We employ one sales professionals for our Baker Cummins brand proprietary skin care products, both of whom are located in Miami, Florida. The lease expired on October 31, 2012 and provided for monthly rentals of approximately \$2,000. We are negotiating a new lease for reduced space.

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. In September 2012, the Company terminated research and development activities at this location, including personnel connected with such efforts and the Company's former consultant, Nian Wu, agreed to use his best efforts to assume such lease pursuant to the terms of his Separation Agreement.

Our corporate headquarters is located at 550 Sylvan Avenue, Englewood Cliffs, New Jersey, where we lease approximately 1,250 square feet of office space. The lease expires on June 30, 2013. Rent expense is approximately \$2,250 per month.

#### **Employees**

We currently employ 66 full time and 35 seasonal employees at our Pittsburg, California facilities, two employees in Englewood Cliffs, New Jersey, one of whom is Mr. Maza, and one employee 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.

### **Legal Proceedings**

Except as set forth below, we are not involved in any pending legal proceeding or litigation that could have a material impact upon our business or results of operations. To the best of our knowledge, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject, which would reasonably be likely to have a material adverse effect on our business or results of operations.

<u>Aphena Pharma Solutions – Maryland, LLC f/k/a Celeste Contract Packaging, LLC, v. BioZone Laboratories, Inc. and BioZone Pharmaceuticals, Inc. and Daniel Fisher</u>

District Court for the District of Maryland Northern Division; Case 1:12-cv-00852-WDQ

An action was commenced on March 19, 2012 against BioZone Labs, the Company and a former officer and director of the Company, Daniel Fisher in the United States District Court for the District of Maryland. The plaintiff alleges breach of contract and other commercial wrongdoing and seeks damages 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. We are unable to provide an estimate of the amount or range of reasonable possible losses from this litigation because, among other reasons, the complaint does not set forth a monetary demand.

<u>Daniel Fisher v. BioZone Pharmaceuticals, Inc., Elliot Maza, Brauser Honig Frost Group, Michael Brauser, Barry Honig, and The Frost Group LLC</u>

United States District Court, Northern District of California, No. 12-03716

On July 16, 2012, Daniel Fisher ("Fisher"), a former officer and director of the Company, commenced an action in the United States District Court for the Northern District of California against the Company and certain officers and investors thereof. Fisher asserts claims for breach of contract, conversion, wrongful termination, and unjust enrichment, and violation of the federal whistleblower statute arising from his former role as an officer and director of the Company and certain contractual agreements that he entered into with the Company. Fisher seeks \$23 million in damages as against all defendants. The Company disputes Fisher's allegations, intends to vigorously defend them and has filed an action against Fisher in New York described below. We are unable to provide an estimate of the amount or range of reasonable possible losses from this litigation because it is at a very early stage.

Supreme Court of the State of New York, County of New York, No. 652489/2012

On July 18, 2012, the Company filed a Summons with Notice in New York State Court against Fisher and 580 Garcia Properties, LLC alleging breach of contract, breach of fiduciary duty, negligence, and fraud claims arising from Fisher's former role as an officer and director of the Company. On November 16, 2012, the Company filed its Complaint in this action that specified the nature and extent of its claims against Fisher. The Company is seeking a minimum of \$2 million in damages, together with the cancellation of 6.65 million shares of the Company's stock, and Fisher's forfeiture of property located at 580 Garcia Avenue, Pittsburg, CA, which property is used by the Company as a warehouse facility.

#### MANAGEMENT

The following persons are our executive officers and directors and hold the positions set forth opposite their respective names.

# **EXECUTIVE OFFICERS AND DIRECTORS**

| Name               | Age | Position   |
|--------------------|-----|--|
| Roberto Prego-Novo | 68  | Chairman   |
| Elliot M. Maza     | 57  | Chief Executive Officer, Chief Financial Officer and Secretary and |
|                    |     | Director   |
| Brian Keller       | 56  | President, Chief Scientific Officer and Director                   |
| Christian Oertle   | 40  | 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. (Inactive), Chief Executive Officer, Chief Financial Officer, Secretary and Director. 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 development stage 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, as Chief Financial Officer from May 2006 until November 2012 and as Consulting Chief Financial Officer from November 2012 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. 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 Strategy Officer. Mr. Oertle serves as our Chief Strategy Officer. Mr. Oertle served as our Chief Operating Officer from June 30, 2011 until February 11, 2013. 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 Bachelors 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 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 be entitled to an annual bonus if the Company met or exceeded criteria adopted by the Board, subject to certain claw back rights. Mr. Fisher's employment agreement had 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. We have paid Mr. Fisher \$ \$49,711 towards the amounts due him under his employment agreement and the remaining balance is \$ 6,133 . Mr. Fisher has claimed approximately \$56,000 in unpaid salary and vacation pay and delivery to him of 6,650,000 shares of the Company's common stock.

#### **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 the section entitled "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, Mr. Maza and Dr. Keller. 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 NYSE MKT LLC, none of Mr. Novo, Mr. Maza and Dr. Keller would be considered an independent director of the Company.

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

Our Board of Directors held one formal meeting during the fiscal year ended December 31, 2011 and no formal meetings during the fiscal year ended December 31, 2012.

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 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.

#### **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<br>Principal<br>Position | Year<br>Ended | Salary<br>(\$) | Bonus<br>(\$) | Stock<br>Awards<br>(\$) | Option<br>Awards<br>(\$) | Non-Equity<br>Incentive Plan<br>Compensation<br>(\$) | All Other<br>Compensation<br>(\$) (1) | Total<br>(\$) |
|-----------------------------------|---------------|----------------|---------------|-------------------------|--------------------------|--|---------------------------------------|---------------|
| Elliot Maza (2)                   | 2010          | 0              | 0             | 0                       | 0                        | 0  | 0                                     | 0             |
|                                   | 2011          | 38,462         | 0             | 0                       | 0                        | 0  | 0                                     | 38,462        |
|                                   | 2012          | 250,000        | 115,800       |                         |                          |  | 23,694                                | 389,494       |
|                                   |               |                |               |                         |                          |  |                                       |               |
| Brian Keller (3)                  | 2010          | 100,000        | 0             | 0                       | 0                        | 0  | 24,771                                | 124,771       |
|                                   | 2011          | 100,000        |               |                         |                          |  | 35,712                                | 135,712       |
|                                   | 2012          | 133,000        | 43,113        |                         |                          |  | 22,848                                | 198,961       |
|                                   |               |                |               |                         |                          |  |                                       |               |
| Daniel Fisher (4)                 | 2010          | 112,000        | 0             | 0                       | 0                        | 3,360 (5)  | 35,149                                | 150,509       |
|                                   | 2011          | 112,000        | 0             | 0                       | 0                        | 0  | 44,702                                | 156,702       |
|                                   | 2012          | 60,667         |               |                         |                          |  | 1,754                                 | 62,421        |
|                                   |               |                |               |                         |                          |  |                                       |               |

| Christian Oertle (6)  | 2010 | 100,000 | 0     | 0 | 0 | 0 | 5,498 | 105,498 |
|---|------|---------|-------|---|---|---|-------|---------|
|   | 2011 | 100,000 | 0     | 0 | 0 | 0 | 4,223 | 104,223 |
|   | 2012 | 100,000 | 5,000 |   |   |   |       |         |
| Roberto Prego-<br>Novo (7)                                  | 2010 | 0       | 0     | 0 | 0 | 0 | 0     | 0       |
|   | 2011 | 0       | 0     | 0 | 0 | 0 | 0     | 0       |
|   | 2012 | 0       | 0     | 0 | 0 | 0 | 0     | 0       |
|   |      |         |       |   |   |   |       |         |
| Eduardo<br>Biancardi<br>President,<br>Secretary, CFO<br>(8) | 2010 | 0       | 0     | 0 | 0 | 0 | 0     | 0       |
|   | 2011 | 0       | 0     | 0 | 0 | 0 | 0     | 0       |
|   | 2012 | 0       | 0     | 0 | 0 | 0 | 0     | 0       |
| Timothy Neely,<br>Chief Operating<br>Officer (9)            | 2010 | 0       | 0     | 0 | 0 | 0 | 0     | 0       |
|   | 2011 | 0       | 0     | 0 | 0 | 0 | 0     | 0       |
|   | 2012 | 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 May 16, 2011, and appointed as Chief Executive Officer on August 2, 2011.
- (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.

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

There were no outstanding equity awards issued to our named executive officers as of December 31, 2012.

#### **Director Compensation**

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

#### **Stock Incentive Plan**

As of December 31, 2012, the Company had not adopted a stock incentive plan.

#### CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Except as described below, during the past three years, there have been no transactions, whether directly or indirectly, between the Company and any of its officers, directors or their family members, that exceeded the lesser of \$120,000 or 1% of the Company's total assets at year end for the last two completed fiscal years.

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. The Company believes Mr. Fisher, our former director and Executive Vice President, directly or indirectly owns 580 Garcia Avenue, LLC. The 580 Garcia Avenue facility is encumbered by mortgage debt of approximately \$2.6 million. BioZone Labs pays approximately \$21,000 per month directly to the mortgage lender, which it treats as rent paid to 580 Garcia Avenue, LLC. The Company believes the property to be worth approximately \$800,000, and that the lease payments for the 580 Garcia Avenue facility are substantially above the market price for similar facilities. In addition, Mr. Fisher claims the Company is indebted to 580 Garcia Avenue, LLC for loans in the aggregate principal amount of approximately \$1.1 million, which Mr. Fisher claims are in default. We paid \$291,528 in rent each year for the years ended December 31, 2011 and 2010.

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 owned approximately 10.63% and 4.62%, 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 a portion of his shares in February and March, 2011 for approximately \$0.027 per share, while the remainders of his shares were acquired through the cashless exercise of warrants he acquired through his purchase of a convertible promissory note in June 2012. Mr. Prego-Novo acquired a portion of his shares in March 2011 for approximately \$0.03 per share, while the remainder were acquired through the cashless exercise of warrants he acquired through his purchase of a convertible promissory note in April 2012. 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 24, 2012, we entered into a securities purchase agreement with Opko Health, Inc., pursuant to which we sold (i) a \$1,700,000 10% secured convertible promissory note due two years from the date of issuance and (ii) ten year warrants to purchase 8,500,000 shares of our common stock at an exercise price of \$0.40 per share for gross proceeds to us of \$1,700,000. The warrants may be exercised on a cashless basis commencing on the issue date. Dr. Philip Frost, the trustee of the Frost Gamma Investments Trust, a holder of 6.07% of our issued and outstanding common stock, is the Chairman and Chief Executive Officer of Opko Health, Inc. On February 28, 2012 and February 29, 2012, we sold an additional \$600,000 of notes and issued warrants on the same terms to purchase an additional 3,000,000 shares of our common stock to additional buyers for gross proceeds to us of \$600,000. 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.

Also on February 24, 2012, BioZone Pharma, BioZone Labs, and Equachem (the "BZL Licensors") and OPKO entered into a Limited License Agreement pursuant to which OPKO acquired an exclusive license to the QuoSomes and EquaSomesTM drug delivery technology for use in ophthalmological indications and a non-exclusive license to such technology for all other indications. Also, on February 24, 2012, BioZone Pharma and OPKO entered into a Distribution Agreement pursuant to which BioZone Pharma appointed OPKO as its exclusive distributor of any drug product containing propofol as an active ingredient in combination with a compound developed by BioZone Labs based on its EquaSomes technology. Frost Gamma Investments Trust is one of our significant shareholders. Dr. Philip Frost is the trustee of Frost Gamma Investments Trust and the Chief Executive Officer of OPKO. The Distribution Agreement was effectively terminated as a result of the Separation Agreement executed between Nian Wu and the Company which, among other things, terminated that certain License Agreement between Mr. Wu and the Company, which provided for the distribution rights granted to OPKO, as further described below.

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. The warrants have an exercise price of \$0.40 per share.

Santana Martinez, one of our former directors, previously provided office space to us at no charge. Our financial statements reflect, as occupancy costs, the fair market value of that space, which is approximately \$150 per month. We treated the usage of the office space as additional paid-in capital and charged the estimated fair value rent of \$150 per month to operations. We recorded total rent expense of \$1,800 for the year ended December 31, 2010 and total rent expense of \$1,800 for the year ended December 31, 2009.

As part of our regular business operations, BioZone Labs purchases raw material ingredients from Equachem and sells finished products to Equalan. The financial statement impact of these intercompany sales and purchases is eliminated in consolidation. Purchases by BioZone Labs from Equachem were approximately \$209,000 and \$158,000 for the years ended December 31, 2010 and 2009, respectively. Sales by BioZone Labs to Equalan were approximately \$190,000 and \$188,000 for the years ended December 31, 2010 and 2009, respectively.

The Company entered into a Separation and Release Agreement with Nian Wu, a consultant to the Company and holder a 6,650,000 shares of the Company's common stock. Under the terms of the Separation Agreement, the parties agreed to terminate the License Agreement dated as of February 12, 2012, granting the Company the right to utilize certain of Mr. Wu's patents relating to "Sugar Lipid Technology" for the potential commercial formulation of Propofol, and the distribution rights granted by the Company to Opko Health, Inc. Mr. Wu also tendered for cancellation 6,650,000 shares of the Company's common stock issued in connection with the acquisition of certain patent rights from Biozone Laboratories, Inc. and affiliates in June 2011. As a result of the foregoing, the Company terminated its research and development activities, including personnel connected with such efforts, in Princeton New Jersey and Mr. Wu agreed to use his best efforts to assume the Company's lease. The Separation Agreement became effective on September 20, 2012 upon acceptance by Opko Health, Inc.

On September 20, 2012, the Company also entered into a Limited License Agreement pursuant to which the Company granted Mr. Wu a limited non-exclusive worldwide license to certain of its patents, originally co-invented by Mr. Wu and assigned to the Company. Under the terms of the Limited License Agreement, each of the Company and Mr. Wu agreed to pay the other a royalty equal to 5% of their respective quarterly net sales of Covered Products (defined as any pharmaceutical preparation or formulation where the manufacture, use, sale, offer for sale, license or assignment thereof relies in whole or in party on any of the patents licensed under the Limited License Agreement) that rely on any Valid Claims (as defined in the Limited License Agreement). Additionally, each of the Company and Mr. Wu agreed to pay the other 50% of all fees or other payments (including all milestones, upfront payments or advances, but excluding royalties on net sales or funding or reimbursement costs of research and development activities) in consideration for any rights granted under a sublicense of the patents assigned under the Limited License Agreement. The Limited License Agreement is effective until the expiration of the last to expire licensed patents unless sooner terminated pursuant to the terms of the License Agreement.

### SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT TO BE UPDATE CLOSER TO FILING

The following tables set forth certain information as of February 12, 2013 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 February 12, 2013, 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.

| Name of Beneficial Owner                                    | Number of Shares<br>Beneficially Owned | Percentage Beneficially<br>Owned (1) |
|---|--|--------------------------------------|
| 5% Owners:  |  | - · · · · · · · · · · · · · · ·      |
| Aero Liquidating Trust (2)                                  |  |                                      |
| 4400 Biscayne Boulevard                                     |  |                                      |
| Miami, Florida 33137  | 8,345,310                              | 12.8%                                |
| OPKO Health, Inc.   |  |                                      |
| 4400 Biscayne Boulevard                                     |  |                                      |
| Miami, Florida 33137  | 7,650,000(3)                           | <u>11.7</u> %                        |
| Daniel Fisher   |  |                                      |
| 36 Marlee Road  |  |                                      |
| Pleasant Hill, CA 94523                                     | 6,650,000                              | 10.2%                                |
| Frost Gamma Investments Trust (4)                           |  |                                      |
| 4400 Biscayne Boulevard                                     | 5 101 500(5)                           | 7.00/                                |
| Miami, Florida 33137  | 5,181,500(5)                           | 7.9%                                 |
| Michael Brauser<br>3700 NF, 27th Ave.                       |  |                                      |
| - / - / / / - / - / - / - / -                               | 4 720 277(6)                           | 7.2%                                 |
| Lighthouse Point, Florida 33064                             | 4,729,377(6)                           | 1.270                                |
| Barry Honig<br>4400 Biscayne Boulevard, Miami, FL 33137     | 3,952,249(7)                           | 6.1%                                 |
| Executive Officers and Directors                            | 3,732,247(1)                           | 0.170                                |
| Brian Keller  | 3,587,500                              | 5.5%                                 |
| Christian Oertle  | 525,000                                | 0.8%                                 |
| Elliot Maza   | 3,587,500                              | 5.5%                                 |
| Roberto Prego-Novo  | 2,939,467(8)                           | 4.5%                                 |
| All executive officers and directors as a group (4 persons) | 10,639,467                             | 16.3%                                |

- 1) Based on 63,142,696 shares of our common stock issued and outstanding as of February 12, 2013.
- 2) James Martin is the trustee of the Aero Liquidating Trust and has sole voting and investment control over the securities held by Aero Liquidating Trust.
- 3) Excludes 8,500,000 shares of common stock underlying a promissory note issued to OPKO Health, Inc. The note can be converted at \$0.20 per share and contains a blocker provision which provides that the note can only be converted such that where the holder would beneficially own a maximum of 4.99% of our outstanding common stock. Dr. Frost is the Chief Executive Officer of OPKO Health Inc. and in such capacity holds voting and dispositive power of such shares held by OPKO Health Inc.

- 4) Dr. Phillip Frost is the trustee of Frost Gamma Investments Trust and in such capacity has sole voting and investment control over the securities held by Frost Gamma Investments Trust. Frost Gamma Limited Partnership is the sole and exclusive beneficiary of Frost Gamma Investments Trust. Dr. Phillip Frost is one of two limited partners of Frost Gamma Limited Partnership. The general partner of Frost Gamma Limited Partnership is Frost Gamma, Inc., and the sole shareholder of Frost Gamma, Inc. is Frost-Nevada Corporation. Dr. Phillip Frost is also the sole shareholder of Frost-Nevada Corporation.
- 5) Excludes 1,776,370 shares of common stock underlying a promissory note issued to Frost Gamma Investments Trust. The note can be converted at \$0.20 per share and contains a blocker provision which provides that the note can only be converted such that where the holder would beneficially own a maximum of 4.99% of our outstanding common stock.
- 6) Includes 270, 629 shares held by Michael Brauser and Betsy Brauser, TBE, 1,273,086 shares held by Grander Holdings Inc. 401K Profit Sharing Plan and 2,885,662 shares held by Michael H. Brauser & Betsy G. Brauser Jt. Tenants. Michael and Betsy Brauser share voting and investment control over the securities held in the name of Michael Brauser and Betsy Brauser, TBE and Michael H. Brauser & Betsy G. Brauser Jt. Tenants. Michael Brauser is the trustee of Grander Holdings Inc. 401K Profit Sharing Plan and has sole voting and investment control over the securities held by Grander Holdings Inc. 401K Profit Sharing Plan. Excludes 500,000 shares of common stock underlying a promissory note issued to Michael Brauser. The note can be converted at \$0.20 per share and contains a blocker provision providing that such note can only converted such that where the holder would beneficially own a maximum of 4.99% of our outstanding common stock.
- 7) Excludes 3,166,667 shares of common stock underlying a promissory notes issued to Barry Honig. The notes can be converted at \$0.20 per share and contains a blocker provision providing that such note can only converted such that where the holder would beneficially own a maximum of 4.99% of our outstanding common stock.
- 8) Includes (i) 2,500,000 shares of common stock held by Olycra Limited Partnership and (ii) 439,467 shares of common stock held by Mr. Prego Novo. Excludes (i) 1,000,000 shares of common stock as to which Mr. Prego-Novo disclaims beneficial ownership, (ii) 500,000 shares of common stock underlying a warrant to purchase common stock issued to Mr. Prego-Novo and (iii) 20,000 shares of common stock underlying a promissory note issued to Mr. Prego-Novo. The warrant can be exercised at an exercise price of \$0.40 per share and the note can be converted at a conversion price of \$0.20 per share. The warrant and note contain blocker provisions providing that they can only converted up to the point where the holder would beneficially own a maximum of 4.99% of our outstanding common stock. Mr. Prego-Novo has sole voting and investment control over the securities held by Olyrca Limited Partnership.

#### SELLING STOCKHOLDER

Up to 8,345,310 shares of common stock are being offered by this prospectus, all of which are being registered for sale for the account of the selling security holder. These shares were originally issued to Aero in connection with an Asset Purchase Agreement dated as of May 16, 2011 by and among the Company, Baker Cummins Corp. and Aero Pharmaceuticals, Inc. In December 2011, Aero transferred the shares to the Aero Liquidating Trust. Upon effectiveness of this Registration Statement, and pursuant to the terms of Asset Purchase Agreement, the Aero Liquidating Trust will distribute the Company's registered shares to its shareholders on a pro rata basis.

The shares of common stock referred to above are being registered to permit public sales of the shares, and the selling stockholder may offer the shares for resale from time to time pursuant to this prospectus. The selling stockholder may also sell, transfer or otherwise dispose of all or a portion of its shares in transactions exempt from the registration requirements of the Securities Act or pursuant to another effective registration statement covering those shares.

The table below sets forth certain information regarding the selling stockholder and the shares of our common stock offered in this prospectus. The selling stockholder has had no material relationship with us within the past three years other than as described in the footnotes to the table below or as a result of its acquisition of our shares or other securities.

Beneficial ownership is determined in accordance with the rules of the SEC. The selling stockholder's percentage of ownership of our outstanding shares in the table below is based upon 63,142,696 shares of Common stock outstanding as of February 12, 2013.

|                            | Ownership Bef                                       | ore Offering          | After Offering (1)                  |   |  |
|----------------------------|---|-----------------------|-------------------------------------|---|--|
|                            | Number of Shares<br>of Common stock<br>Beneficially | Number of             | Number of Shares of<br>Common stock | Percentage of Common stock Beneficially |  |
| Selling Stockholder        | Owned   | <b>Shares Offered</b> | <b>Beneficially Owned</b>           | Owned                                   |  |
| Aero Liquidating Trust (2) | 8,345,310   | 8,345,310             | 0                                   | 0%                                      |  |
| Total                      | _   | 8,345,310             |                                     | _                                       |  |

- (1) Represents the amount of shares that will be held by the selling stockholder after completion of this offering based on the assumptions that (a) all shares registered for sale by the registration statement of which this prospectus is part will be sold and (b) no other shares of our common stock are acquired or sold by the selling stockholder prior to completion of this offering. However, the selling stockholder may sell all, some or none of the shares offered pursuant to this prospectus and may sell other shares of our common stock that they may own pursuant to another registration statement under the Securities Act or sell some or all of their shares pursuant to an exemption from the registration provisions of the Securities Act, including under Rule 144. To our knowledge there are currently no agreements, arrangements or understanding with respect to the sale of any of the shares that may be held by the selling stockholder after completion of this offering or otherwise, other than the Asset Purchase Agreement with Aero, which requires the distribution of unsold shares to the shareholders of Aero on the date of liquidation of Aero. As such, the shareholders of Aero receiving registered shares may also be considered to be selling shareholders under this prospectus at such time as they receive such shares.
- (2) James Martin is the trustee of the Aero Liquidating Trust and, as such, has sole voting and investment power over the shares held by the Aero Liquidating Trust.

#### **DESCRIPTION OF SECURITIES**

#### **Authorized Capital Stock**

We have authorized 100,000,000 shares of capital stock, par value \$0.001 per share, all of which are designated as common stock.

#### **Capital Stock Issued and Outstanding**

As of February 12, 2013, there were issued and outstanding:

· 63,142,696 shares of common stock;

- · Warrants to purchase (i) 1,000,000 shares of common stock at an exercise price of \$1.00 per share, (ii) 1,105,000 shares of common stock at an exercise price of \$0.60 per share
- · Notes convertible into 13,776,370 shares of common stock at a conversion price of \$0.20 per share, and notes convertible into 333,333 shares of common stock at a conversion price of \$1.50 per share.

#### Common Stock

The holders of the common stock will be entitled to one vote per share. In addition, the holders of the common stock will be entitled to receive ratably such dividends, if any, as may be declared by our Board of Directors out of legally available funds; however, the current policy of our Board of Directors is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of the common stock will be entitled to share ratably in all assets that are legally available for distribution. The holders of the Common Stock will have no preemptive, subscription, redemption or conversion rights.

#### **Dividend Policy**

We have not previously paid any cash dividends on our common stock and do not anticipate or contemplate paying dividends on our common stock in the foreseeable future. We currently intend to use all our available funds to develop our business. We can give no assurances that we will ever have excess funds available to pay dividends.

#### **Transfer Agent**

The transfer agent for our common stock is Equity Stock Transfer.

#### Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

There have been no changes in or disagreements with our accountants since our formation required to be disclosed pursuant to Item 304 of Regulation S-K, except those that have been previously reported in our filings with the Securities and Exchange Commission.

#### **Indemnification of Directors and Officers**

Nevada Revised Statutes ("NRS") Sections 78.7502 and 78.751 provide us with the power to indemnify any of our directors and officers. The director or officer must have conducted himself/herself in good faith and reasonably believe that his/her conduct was in, or not opposed to, our best interests. In a criminal action, the director, officer, employee or agent must not have had reasonable cause to believe his/her conduct was unlawful.

Under NRS Section 78.751, advances for expenses may be made by agreement if the director or officer affirms in writing that he/she believes he/she has met the standards and will personally repay the expenses if it is determined such officer or director did not meet the standards.

Our Bylaws include an indemnification provision under which we have the power to indemnify our directors, officers, former directors and officers, or any person who serves or served at our request for our benefit as a director or officer of another corporation or our representative in a partnership, joint venture, trust, or other enterprise (including heirs and personal representatives) against all expenses, liability, and loss actually and reasonably incurred.

We also have a director and officer indemnification agreement with our Chairman that provides, among other things, for the indemnification to the fullest extent permitted or required by Nevada law, provided that such indemnity shall not be entitled to indemnification in connection with any "claim" (as such term is defined in the agreement) initiated by the indemnity against us or our directors or officers unless we join or consent to the initiation of such claim, or the purchase and sale of securities by the indemnity in violation of Section 16(b) of the Exchange Act.

Any repeal or modification of these provisions approved by our stockholders shall be prospective only, and shall not adversely affect any limitation on the liability of any of our directors or officers existing as of the time of such repeal or modification.

We are also permitted to apply for insurance on behalf of any director, officer, employee or other agent for liability arising out of his actions, whether or not the NRS would permit indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

#### **Limitation of Liability of Directors**

Our Amended and Restated Articles of Incorporation provides a limitation of liability such that no director or officer shall be personally liable to us or any of our stockholders for damages for breach of fiduciary duty as a director or officer, involving any act or omission of any such director or officer, provided there was no intentional misconduct, fraud or a knowing violation of the law, or payment of dividends in violation of NRS Section 78.300.

#### PLAN OF DISTRIBUTION

This prospectus includes 8,345,310 shares of common stock offered by the selling stockholder, the Aero Liquidating Trust. The securities were original issued to Aero pursuant to an Asset Purchase Agreement dated as of May 16, 2011 by and among the Company, Baker Cummins Corp., a Nevada corporation, and Aero (the "APA"). In December 2011, Aero transferred these shares to the Aero Liquidating Trust, which is holding the shares for the benefit of the holders of the common stock of Aero of record (the "Aero Record Holders")

In accordance with Section 7.2 of the APA, which is incorporated by reference herein, the Aero Liquidating Trust shall distribute its shares of common stock to the Aero Record Holders pursuant to the plan of liquidation, which is contemplated by the APA.

The Aero Liquidating Trust intends to make a pro-rata distribution to the Aero Record Holders of the shares of common stock of the Company, which were originally acquired by Aero in connection with the APA. Presently, Aero has 111,145,001 shares of common stock outstanding, and the Aero Liquidating Trust owns 8,331,396 shares of the Company's common stock (out of approximately 63,142,696 shares outstanding). The Company has informed Aero and the Aero Liquidating Trust that it will make a cash payment, in lieu of issuing fractional shares, to the Aero Record Holders who would otherwise be entitled to receive fractional shares upon the distribution by the Aero Liquidating Trust of its shares of the Company's common stock. The Company will deliver such cash amount to the Aero Liquidating Trust so that it will pay such cash amount directly to the Aero Record Holders at the time it makes its distribution to the Aero Record Holders. Distribution of these shares will be made subsequent to the SEC declaring effective the Registration Statement on Form S-1 registering for resale the shares of the Company's Common Stock held by the Aero Liquidating Trust, of which this Prospectus forms a part.

As a result, the Aero Liquidating Trust will pay to each Aero Record Holder a pro-rata distribution of shares of the Company's common stock owned by the Aero Liquidating Trust, including the fractional cash amount to be paid by the Company to Aero Record Holders entitled to receive fractional shares of the Company's common stock upon the pro-rata distribution of shares of the Company's common stock owned by the Aero Liquidating Trust based on the contemplated 1 for-13.3 exchange ratio (based on the number of outstanding shares of Aero common stock and the number of shares of the Company's common stock held by the Aero Liquidating Trust, one whole share of the Company's common stock will be distributed for approximately 13.3 shares of Aero common stock).

The final distribution, including the payment of the fractional cash amount is in complete cancellation of Aero's common stock.

#### LEGAL MATTERS

Sichenzia Ross Friedman and Ference LLP, New York, New York, will pass upon the validity of the shares of our common stock to be sold in this offering.

#### **EXPERTS**

The financial statements for the fiscal year ending December 31, 2011 included in this prospectus have been audited by Paritz and Co. P.A., an independent registered public accounting firm as set forth in their report, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

#### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1, together with any amendments and related exhibits, under the Securities Act with respect to our shares of Common stock offered by this prospectus. The registration statement contains additional information about us and the shares of Common stock that we are offering in this prospectus.

We file annual, quarterly and current reports and other information with the SEC under the Exchange Act. You may request a copy of those filings, excluding exhibits, from us at no cost. These requests should be addressed to us at: Elliot Maza, Chief Executive Officer and Chief Financial Officer, BioZone Pharmaceuticals, Inc., 550 Sylvan Avenue, Suite 101, Englewood Cliffs, NJ 07632. Our telephone number is (201) 608-5101. The public may read and copy any materials filed by the Company with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at <a href="https://www.sec.gov">www.sec.gov</a>. The contents of these websites are not incorporated into this filing by reference. Further, the Company's references to the URLs for these websites are intended to be inactive textual references only.

# BIOZONE PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS

|  | September 30, 2012 (Unaudited) | <b>December 31, 2011</b> |
|--|--------------------------------|--------------------------|
| ASSETS   |                                |                          |
|  |                                |                          |
| Current assets:  |                                |                          |
| Cash and cash equivalents  | \$ 82,621                      | \$ 416,333               |
| Account receivable net of allowance for doubtful accounts \$163,339 and \$449,524,       | 010 502                        | 522 020                  |
| respectively   | 919,503                        | 523,039                  |
| Inventories  | 2,151,779                      | 1,819,751                |
| Prepaid expenses and other current assets  | 489,663                        | 145,313                  |
| Total current assets   | 3,643,566                      | 2,904,436                |
|  | 2 244 426                      | 2 2 4 2 4 4 7            |
| Property and equipment, net  | 3,344,426                      | 3,342,447                |
| Deferred financing costs, net  | 39,900                         | 25,319                   |
| Goodwill   | 1,026,984                      | 1,026,984                |
| Intangibles, net   | 205,033                        | 247,450                  |
|  | 4,616,343                      | 4,642,200                |
| Total Assets   | \$ 8,259,909                   | \$ 7,546,636             |
| Total Assets   | \$ 6,237,707                   | 7,540,030                |
| LIABILITIES AND SHAREHOLDERS' DEFICIENCY   |                                |                          |
| LIABILITIES AND SHAREHOLDERS DEFICIENCY  |                                |                          |
| Current liabilities:   |                                |                          |
| Account payable  | 1,019,189                      | 1,616,673                |
| Accrued expenses and other current liabilities   | 991,596                        | 1,181,852                |
| Accrued interest   | 191,728                        | 83,548                   |
| Notes payable - shareholder  | 1,099,715                      | 1,099,715                |
| Convertible notes payable  | 1,227,743                      | 2,050,000                |
| Deferred income tax  | 102,022                        | 102,022                  |
| Derivative instruments   | 595,104                        | 883,619                  |
| Current portion of long term debt  | 194,247                        | 260,741                  |
| Total current liabilities  | 5,421,344                      | 7,278,170                |
|  |                                | ,,_,,,,,,                |
| Long Term Debt   | 2,913,492                      | 3,037,591                |
|  |                                |                          |
| Shareholders' deficiency   |                                |                          |
| Common stock, \$.001 par value, 100,000,000 shares authorized, 63,142,969 and 55,181,165 |                                |                          |
| shares issued and outstanding at September 30, 2012, and December 31, 2011, respectively |                                | 55,181                   |
| Additional paid-in capital   | 10,484,611                     | 3,339,171                |
| Accumulated deficit  | (10,622,681)                   | (6,163,477)              |
| Total showshaldows! definionary  | (74.027)                       | (2.7(0.125)              |
| Total shareholders' deficiency   | (74,927)                       | (2,769,125)              |
| Total liabilities and shareholders' deficiency   | \$ 8,259,909                   | \$ 7,546,636             |

See accompanying notes to consolidated financial statements

### BIOZONE PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

|  | Three Months Ended September 30, |             |    |             | Nine Months Ended September 30, |             |    |             |
|--|----------------------------------|-------------|----|-------------|---------------------------------|-------------|----|-------------|
|  |                                  | 2012        |    | 2011        |                                 | 2012        |    | 2011        |
| Sales  | \$                               | 4,893,758   | \$ | 3,930,503   | \$                              | 13,315,944  | \$ | 8,937,818   |
| Cost of sales  |                                  | (2,871,266) |    | (1,845,127) |                                 | (7,817,619) |    | (5,209,891) |
| Gross profit   |                                  | 2,022,492   |    | 2,085,376   |                                 | 5,498,325   |    | 3,727,927   |
| Operating Expenses:  |                                  |             |    |             |                                 |             |    |             |
| General and administrative expenses                          |                                  | 1,373,148   |    | 4,084,866   |                                 | 4,285,021   |    | 6,216,528   |
| Selling expenses   |                                  | 131,085     |    | 212,791     |                                 | 595,622     |    | 497,938     |
| Research and development expenses                            |                                  | 155,941     |    | 4,011       |                                 | 584,059     |    | 119,167     |
| Total Operating Expenses                                     |                                  | 1,660,174   |    | 4,301,668   |                                 | 5,464,702   |    | 6,833,633   |
| Income (Loss) from operations                                |                                  | 362,318     |    | (2,216,292) |                                 | 33,623      |    | (3,105,706) |
| Interest expense   |                                  | (482,960)   |    | (283,411)   |                                 | (4,970,657) |    | (505,606)   |
| Change in fair market value of derivative liability          |                                  | 21,912      |    | _           |                                 | 477,830     |    |             |
|  |                                  |             |    |             |                                 |             |    |             |
| Loss before income taxes                                     |                                  | (98,730)    |    | (2,499,703) |                                 | (4,459,204) |    | (3,611,312) |
| Income taxes   |                                  | _           |    | _           |                                 | _           |    | _           |
| Net loss   | \$                               | (98,730)    | \$ | (2,499,703) | \$                              | (4,459,204) | \$ | (3,611,312) |
| Net loss per common share                                    | \$                               | (0.00)      | \$ | (0.04)      | \$                              | (0.07)      | \$ | (0.10)      |
|  |                                  |             |    |             |                                 |             |    |             |
| Basic and diluted weighted average common shares outstanding |                                  | 69,418,903  | _  | 67,443,800  | _                               | 61,631,047  | _  | 36,667,874  |

See accompanying notes to consolidated financial statements

# BIOZONE PHARMACEUTICAL, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

|   | Nine Months Ended September 30 |             |    | eptember 30, |
|---|--------------------------------|-------------|----|--------------|
|   |                                | 2012        |    | 2011         |
| Cook Same from an anti-ities  |                                |             |    |              |
| Cash flows from operating activities Net loss                               | \$                             | (4,459,204) | \$ | (3,611,312)  |
| Adjustments to reconcile net loss to net cash used in operating activities: | Ф                              | (4,439,204) | Ф  | (3,011,312)  |
|   |                                |             |    |              |
| Bad debt expense  |                                | 99,803      |    | 25,000       |
| Depreciation & Amortization   |                                | 360,554     |    | 372,002      |
| Amortization of financing costs   |                                | 21,723      |    | _            |
| (Loss) on change in fair value of derivative liability                      |                                | (477,830)   |    | _            |
| Stock and warrant based compensation  |                                | 120,000     |    | 1,950,000    |
| Non-cash interest expense   |                                | 4,742,188   |    | _            |
| Changes in assets and liabilities:  |                                |             |    |              |
| Account receivable-trade  |                                | (496,267)   |    | (430,999)    |
| Inventories   |                                | (332,028)   |    | (791,677)    |
| Prepaid expenses and other current assets                                   |                                | (344,350)   |    | (16,933)     |
| Accounts payable  |                                | (597,484)   |    | 1,753,882    |
| Accrued expenses and other current liabilities                              |                                | (273,804)   |    | 709,051      |
| Net cash used in operating activities                                       |                                | (1,636,699) |    | (40,986)     |
| Coate Coare in continuous in this   |                                |             |    |              |
| Cash flows from investing activities  |                                | (320,116)   |    | (157.5(0)    |
| Purchase of property and equipment  Cash acquired on business combination   |                                | (320,116)   |    | (157,568)    |
|   |                                | (220.116)   |    | 585,720      |
| Net cash used in investing activities                                       |                                | (320,116)   | _  | 428,152      |
| Cash flows from financing activities  |                                |             |    |              |
| Proceeds from convertible debt  |                                | 3,750,000   |    | 2,750,000    |
| Proceeds from sale of common stock  |                                | 650,000     |    | _            |
| Payment of deferred financing costs   |                                | (36,304)    |    | (150,364)    |
| Repayment of debt   |                                | (190,593)   |    | (2,453,341)  |
| Repayment of borrowings from noteholders                                    |                                | (2,550,000) |    | _            |
| Advance from (payment to) shareholder                                       |                                |             |    | (3,211)      |
| Net cash provided by financing activities                                   |                                | 1,623,103   |    | 143,084      |
| Net increase (decrease) in cash and cash equivalents                        |                                | (333,712)   |    | 530,250      |
| Code and and and advantage becomes of anick                                 |                                | 417.222     |    | 251 475      |
| Cash and cash equivalents, beginning of period                              |                                | 416,333     | _  | 251,475      |
| Cash and cash equivalents, end of period                                    | \$                             | 82,621      | \$ | 781,725      |
| Supplemental disclosures of cash flow information:                          |                                |             |    |              |
| Interest paid   | \$                             | 312,232     | \$ | 319.872      |
| Debt discount from warrant liability  | \$                             | 2,755,274   | \$ | 517,072      |
| Cashless exercise of warrants for common stock                              | \$                             | 6,503,201   | \$ |              |
| Cashess exercise of waitants for confinion stock                            | 3                              | 0,505,201   | Φ  |              |

See accompanying notes to consolidated financial statements

#### BioZone Pharmaceuticals. Inc.

Notes To Consolidated Financial Statements September 30, 2012 (Unaudited)

#### 1. Basis of Presentation

The accompanying unaudited consolidated financial statements presented herein have been prepared in accordance with the instructions to Form 10-Q and do not include all the information and note disclosures required by accounting principles generally accepted in the United States. The consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 filed with the Securities and Exchange Commission (the "SEC") on April 16, 2012. In the opinion of management, this interim information includes all material adjustments, which are of a normal and recurring nature, necessary for fair presentation.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Estimates that are particularly susceptible to change include assumptions used in determining the fair value of securities owned and non-readily marketable securities.

The Consolidated Statements of Operations for the three and nine months ended September 30, 2012 and 2011 contains a revised presentation of Net loss per common share and Basic and diluted weighted average common shares outstanding for each period presented as compared to such amounts included on Form 10-Q for the period September 30, 2012 filed on November 14, 2012. The following table describes the revisions:

|  | Three months ended<br>September 30, 2011 | Nine months ended<br>September 30, 2011 |
|--|--|---|
| Net loss per common share - originally reported                                    | (0.04)                                   | (0.07)                                  |
| Basic and diluted weighted average common shares outstanding - originally reported | 67,492,714                               | 49,112,016                              |
| Net loss per common share - adjusted   | (0.04)                                   | (0.10)                                  |
| Basic and diluted weighted average common shares outstanding - adjusted            | 67,443,800                               | 36,667,874                              |

The revised presentation in the Consolidated Statements of Operations for the three and nine months ended September 30, 2012 and 2011 arises from a revision of the number of shares outstanding as of December 31, 2009, the first date of the Company's financial statements included in this Amendment No. 8 to Form S-1. Specifically, we reduced the number of shares outstanding as of December 31, 2009 from 44,749,999 to 21,000,000 to accurately reflect the number of shares issued to the owners of the BioZone Labs Group, the accounting acquiror in the reverse merger.

The results of operations for the three and nine months ended September 30, 2012, are not necessarily indicative of the results to be expected for the entire year or for any other period.

#### 2. Business Description and Going Concern

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 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 Laboratories, LLC ("BetaZone") in exchange for 321,101 shares of our common stock, for a total of 21 million shares. 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. We have 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 historical financial statements of the BioZone Lab Group, and BioZone Pharmaceuticals, Inc. from the date of acquisition. As a result of the June 30, 2011 transaction referred to above, we recorded the fair value of the acquisition at \$2,000,000 as further described below. In addition, on September 21, 2011, the Company issued 13,914 shares of common stock to certain shareholders in consideration for the delay in filing the Company's Registration Statement on Form S-1, as required in the Asset Purchase Agreement. These shares were valued at \$0.50 per share and the resulting amount was charged to interest expense at the time of issuance.

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 acquired 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 June 30, 2011 as follows:

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

#### 3. Summary of Significant Accounting Policies

**Revenue Recognition.** We follow the guidance of the SEC'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.

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

The Company considered the terms of its interest in 580 Garcia and determined that 580 Garcia is a VIE in accordance with ACS 810-10-55, which should be consolidated. As of September 30, 2012, amounts included in the consolidated assets relating to 580 Garcia, which are shown in property and equipment, and consolidated liabilities, which are reported in long-term debt, total \$766,205 and \$2,613,675, respectively. The Company's involvement with the entity is limited to its lease to rent the facility from 580 Garcia, with the Company as the only tenant, and the guarantee of the mortgage loan on the property of 580 Garcia. The Company's maximum exposure to loss, based on the Company's guarantee of the mortgage loan of 580 Garcia, is \$2,613,675, which equals the carrying amount of the liability as of September 30, 2012.

Our investment in Betazone, which is our significant unconsolidated subsidiary, is accounted for using the equity method of accounting.

Convertible Instruments . We evaluate and account for conversion options embedded in convertible instruments in accordance with ASC 815 "Derivatives and Hedging Activities". Applicable Generally Accepted Accounting Principles ("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.

Common Stock Purchase Warrants. 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 shares of our common stock were valued using the Black-Scholes option pricing model, using the following assumptions at September 30, 2012:

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

**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.

**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                   | September 30,<br>2012 | December 31,<br>2011 |
|--------------------------|-------------------------------|-----------------------|----------------------|
| Vehicles                 | 5 years                       | 300,370               | 300,370              |
| Furniture and Fixtures   | 10 years                      | 64,539                | 60,936               |
| Computers                | 5 years                       | 192,413               | 191,206              |
| MFG equipment            | 10 years                      | 4,062,593             | 3,967,302            |
| Lab Equipment            | 10 years                      | 988,122               | 821,639              |
| Bldg/Leasehold           | 19 years (remainder of lease) | 1,655,853             | 1,608,055            |
| Building                 | 40 years                      | 571,141               | 571,141              |
| Land                     | Not depreciated               | 380,000               | 380,000              |
|                          | •                             | 8,215,031             | 7,900,649            |
| Accumulated depreciation |                               | (4,870,605)           | (4,558,202)          |
| Net                      |                               | 3,344,426             | 3,342,447            |

**5. Equity Method Investments.** Our investment in Betazone, which is our significant unconsolidated subsidiary, is accounted for using the equity method of accounting. Summarized financial information for our investment in Betazone assuming 100% ownership interest is as follows:

|                         | September 30,<br>2012 | <b>December 31, 2011</b> |
|-------------------------|-----------------------|--------------------------|
| Balance sheet           |                       |                          |
| Current assets          | 9,768                 | 124,462                  |
| Current liabilities     | 264,199               | 131,672                  |
|                         |                       |                          |
| Statement of operations |                       |                          |
| Revenues                | 29,534                | 315,346                  |
| Net loss                | (229,323)             | (102,047)                |

In 2011, the Company's share of Betazone's losses became equal in amount to the carrying value of its investment in Betazone. Accordingly, the Company suspended the equity method of accounting for its investment and no additional losses were charged to operations. The Company's unrecorded share of losses for the nine months ended September 30, 2012 totaled \$103,195.

#### 6. Convertible Notes Payable

The "March 2011 Notes"

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

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. The entire principal amount and any accrued and unpaid interest was due and payable in cash on such 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 was dependent on the closing date of, and the price of securities issued in the Target Transaction Financing, which had yet to take place.

Effective October 28, 2011, the holders of the March 2011 Notes agreed to extend the maturity date of the March 2011 Notes (the "Extension Agreement") to October 29, 2011. As consideration for the agreement by the holders to enter into the Extension Agreement, the Company (i) issued to the holders an aggregate of 112,500 shares of its common stock, and (ii) paid to the holders an aggregate of \$129,000 of interest for the period beginning on February 28, 2011 (the date the 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 of common stock on the same terms and conditions provided for the securities required to be registered pursuant to the registration rights obligations by the Company under the private placement transaction documents.

The Company agreed that if it failed to repay the March 2011 Notes on or before the amended maturity date, then in addition to the interest due under the March 2011 Notes, the Company would pay an additional 2% penalty (annualized) for each 30 day period during which all or any portion of the principal or accrued interest remains 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% penalty 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 amended maturity date and then upon each 30 day anniversary of the amended 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 remaining 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 2011 Warrant") to purchase certain securities of the Company in the Target Transaction Financing, pursuant to a Securities Purchase Agreement entered into on that date.

On November 30, 2011, the holder of the September 2011 Note converted the entire principal amount and accrued interest due with respect to the September 2011 Note into 1,018,356 shares of our common stock. In addition, we issued to the holder a warrant to purchase 500,000 shares of our common stock at an exercise price of \$1.00 per share.

The "February 2012 Notes"

On February 24, 2012, we entered into a Securities Purchase Agreement with OPKO Health Inc. pursuant to which we sold a 10% secured convertible promissory note in the aggregate principal amount of \$1,700,000 due two years from the date of issuance and issued warrants to purchase 8,500,000 shares of the our common stock, at an exercise price of \$0.40 per share, for gross proceeds of \$1,700,000.

On February 28, 2012 and February 29, 2012, we entered in a Securities Purchase Agreement with two additional buyers pursuant to which we sold an additional \$600,000 aggregate principal amount of notes and issued warrants to purchase an additional 3,000,000 shares of our common stock, at an exercise price of \$0.40 per share, for gross proceeds of \$600,000, on the same terms as the notes and warrants issued to OPKO as described above.

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 pursuant to which all of our obligations under the notes are secured by a first priority perfected security interest in all of our tangible and intangible assets, including all of our ownership interest in our subsidiaries.

The entire principal amount and any accrued and unpaid interest on the notes is due and payable in cash on the maturity date set forth in the notes. The notes bear interest at the rate of 10% per annum. The notes are convertible into shares of our common stock at an initial conversion price of \$0.20 per share, subject to adjustment. We 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, our failure to pay any accrued but unpaid interest when due, the failure to perform any obligation under the governing transaction documents or if any representation or warranty made by the Company in connection with the governing transaction documents proves to have been incorrect in any material respect constitutes an Event of Default under the governing transaction documents.

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 holder 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.

The warrants are immediately exercisable and expire ten years after the date of issuance. The warrants have an initial exercise price of \$0.40 per share. The warrants are exercisable in cash or through a "cashless exercise". All of the warrants granted with these notes have been exercised.

We determined that the initial fair value of the warrants was \$5,221,172 based on the Black-Scholes option pricing model, which we treated as a liability with a corresponding decrease in the carrying value of the notes. Under authoritative guidance, the carrying value of the notes may not be reduced below zero. Accordingly, we recorded interest expense of \$2,921,172 at the time of the issuance of the notes, which is the excess of the value of the warrants over the allocated fair value of the notes. The discount related to the notes will be amortized over the term of the notes as interest expense, calculated using an effective interest method.

We determined that, according to ASC 470120-30, a beneficial conversion feature existed based on the intrinsic value of the conversion feature. Due to the fact that the carrying amount of the convertible notes has been reduced to zero, based on the discount allocated from the value of the warrants referred to above, that no beneficial conversion feature is to be recorded. ASC 470-20-30-8 states that if the intrinsic value of the beneficial conversion feature is greater than the proceeds allocated to the convertible instrument, the amount of the discount assigned to the beneficial conversion feature shall be limited to the amount of the proceeds allocated to the convertible instrument.

The "March 2012 Purchase Order Notes"

On March 13, 2012, we sold a 10% senior convertible promissory note with a principal amount of \$1,000,000 (the "Purchase Order Note") to an accredited investor for a purchase price of \$1,000,000. The principal amount of the Purchase Order Note is payable in cash on such dates and in such amounts as set forth in the Purchase Order Note, based on the receipt of proceeds from sales to a certain vendor (the "Vendor Proceeds"). The last date of the scheduled payments under the Purchase Order Note is referred to as the "Final Maturity Date". All of our obligations under the Purchase Order Note are secured by a first priority security interest in the Vendor Proceeds. The holder of the notes issued in February 2012 agreed to subordinate their security interest in the Vendor Proceeds to the interest of the holder of the Purchase Order Note.

The Purchase Order Note is convertible into shares of our common stock at an initial conversion price of \$1.50 per share. The Purchase Order Note bears interest at the rate of 10% per annum. We may prepay any outstanding amounts owing under the Purchase Order 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 is 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 and (3) the occurrence of an Event of Default (as defined in the Purchase Order Note).

The Company has not recorded a BCF on the March 201 2 Purchase Order Notes due to the effective conversion price being greater than the fair value of the Company's stock at the issuance date.

The Company is prohibited from effecting a conversion of the Purchase Order Note, to the extent that as a result of such conversion, the holder 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 Purchase Order Note.

As of September 30, 2012, the Company repaid \$500,000 of the Purchase Order Note.

The "April 2012 Working Capital Notes"

On April 18, 2012, we sold a 10% senior convertible promissory note with a principal amount of \$250,000 (the "Working Capital Note") to an accredited investor for a purchase price of \$250,000. The principal amount of the Working Capital Note is payable in cash on such dates and in such amounts as set forth in the Working Capital Note based on the receipt of the Vendor Proceeds. The last date of the scheduled payments under the Working Capital Note is referred to as the "Final Maturity Date". All of our obligations under the Purchase Order Note are secured by a first priority security interest in the Vendor Proceeds. The buyers of the February 2012 Notes agreed to subordinate their security interest in the Vendor Proceeds to the interest of the holder of the Working Capital Note.

The Working Capital Note is convertible into shares of our common stock at an initial conversion price of \$1.50 per share. The Working Capital Note bears interest at the rate of 10% per annum. We may prepay any outstanding amounts owing under the Working Capital 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 is 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 and (3) the occurrence of an Event of Default (as defined in the Working Capital Note).

The Company is prohibited from effecting a conversion of the Working Capital Note, to the extent that as a result of such conversion, the holder 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 Working Capital Note.

On September 28, 2012, the holder of the Working Capital Note exchanged such note for the June 2012 Convertible Notes described below.

The "June 2012 Working Capital Notes"

On June 13, 2012, we sold 10% promissory notes with an aggregate principal amount of \$200,000 (the "June 2012 Working Capital Notes") to accredited investors for an aggregate purchase price of \$200,000. The principal amount of the June 2012 Working Capital Notes is payable in cash on the date that is the earlier of receipt by the Company of \$500,000 or more from any source (other than sales in the ordinary course of business) or three months from the issuance date.

The June 2012 Working Capital Notes bear interest at the rate of 10% per annum. We may prepay any outstanding amounts owing under the June 2012 Working Capital Notes, in whole or in part, at any time prior to the maturity date.

On June 28, 2012, the holders of the June 2012 Working Capital Notes exchanged such notes for the June 2012 Convertible Notes described below.

The "June 2012 Convertible Notes"

On June 28, 2012, we issued 10% convertible promissory notes (the "June 2012 Convertible Notes") with an aggregate principal amount of \$455,274 and warrants (the "June 2012 Warrants") to purchase 2,250,000 shares of our common stock at an exercise price of \$0.40 per share to the holders of the Working Capital Notes and June 2012 Working Capital Notes with an aggregate amount of principle and accrued interest due as of such date equal to the aggregate principle amount of the June 2012 Convertible Notes. The Working Capital Notes and June 2012 Working Capital Notes were cancelled.

The June 2012 Convertible Notes bear interest at the rate of 10% per annum and mature two years from their issue date. We may prepay any outstanding amounts owing under the June 2012 Convertible Notes, in whole or in part, at any time prior to the maturity date. The entire remaining principal amount and all accrued but unpaid or unconverted interest is due and payable on the earlier of the Maturity Date or the occurrence of an Event of Default (each as defined in the June 2012 Convertible Notes). The June 2012 Convertible Notes are convertible into shares of our common stock at an initial conversion price of \$0.20 per share.

The Company is prohibited from effecting a conversion of the June 2012 Convertible Notes or exercise of the June 2012 Warrants, to the extent that as a result of such conversion or exercise, the holder 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 June 2012 Convertible Note or exercise of the June 2012 warrant, as the case may be.

The June 2012 Warrants are exercisable immediately and expire ten years after the date of issuance and have an initial exercise price of \$0.40 per share. The June 2012 Warrants are exercisable in cash or through a "cashless exercise". We determined that the initial fair value of the June 2012 Warrants was \$1,036,042 based on the Black-Scholes option pricing model, which we treated as a liability with a corresponding decrease in the carrying value of the June 2012 Convertible Notes. Under authoritative guidance, the carrying value of the June 2012 Convertible Notes may not be reduced below zero. Accordingly, we recorded interest expense of \$580,768, which is the excess of the value of the June 2012 Warrants over the allocated fair value of the June 2012 Convertible Notes, at the time of the issuance of the June 2012 Convertible Notes. The discount related to the June 2012 Convertible Notes will be amortized over the term of the Notes as interest expense, calculated using an effective interest method.

We determined that, according to ASC 470120-30, a beneficial conversion feature existed based on the intrinsic value of the conversion feature. Due to the fact that the carrying amount of the convertible notes has been reduced to zero, based on the discount allocated from the value of the warrants referred to above, that no beneficial conversion feature is to be recorded. ASC 470-20-30-8 states that if the intrinsic value of the beneficial conversion feature is greater than the proceeds allocated to the convertible instrument, the amount of the discount assigned to the beneficial conversion feature shall be limited to the amount of the proceeds allocated to the convertible instrument.

The following table sets forth a summary of all the outstanding convertible promissory notes at September 30, 2012:

| Convertible promissory notes issued    | 6,505,274   |
|--|-------------|
| Notes repaid                           | (2,750,000) |
| Less amounts converted to common stock | (500,000)   |
|  | 3,255,274   |
| Less debt discount                     | 2,027,531   |
| Balance September 30, 2012             | 1,227,743   |

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.

#### **8. Long Term Debt.** Long-term debt consists of:

|   | ç  | 9/30/2012 | 1  | 2/31/2011 |
|---|----|-----------|----|-----------|
| Notes payable of Biozone Labs   |    |           |    |           |
| 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   | \$ | 190,826   | \$ | 307,255   |
| City of Pittsburg Redevelopment Agency, 3% interest, payable in monthly installments of \$3,640 inclusive |    |           |    |           |
| of interest   |    | 233,527   |    | 257,639   |
| Other   |    | 85,000    |    | 90,000    |
| Notes payable of 580 Garcia Properties  |    |           |    |           |
| 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  |    | 2,598,386 |    | 2,643,438 |
|   |    | 3,107,739 |    | 3,298,332 |
| Less: current portion   |    | 194,247   |    | 260,741   |
|   | \$ | 2,913,492 | \$ | 3,037,591 |

#### 9. Warrants

The "March 2011 Warrants"

In March, 2011, the Company issued the March 2011 Warrants to purchase securities of the Company in the Target Transaction Financing as defined in the governing purchase agreement (Note 7).

The March 2011 Warrants may be exercised immediately and expire five years after the date of issue. Each March 2011 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 March 2011 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 below) (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 March 2011 Warrant is exercisable in cash or by way of a "cashless exercise" during any period that a registration statement covering the resale of the underlying shares of common stock and/or other securities issuable upon exercise of the March 2011 Warrant, or an exemption from registration is not available. The exercise price of the March 2011 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 March 2011 Warrant will be immediately reduced to equal the price at which the Company issued the securities.

On February 28, 2012, each holder of March 2011 Warrants entered into a Cancellation Agreement, which provides, among other things, for the cancellation of the March 2011 Warrants. In exchange, the Company issued to the former holders of the March 2011 Warrants a total of 1,000,000 replacement warrants (the "Replacement Warrants"). The Replacement Warrants may be exercised immediately and expire four years after the date of issue. Each Warrant has an initial exercise price of \$0.60 per share, subject to adjustment for certain corporate reorganization transactions.

As of September 30, 2012, a total of 1,000,000 Replacement Warrants remain outstanding, with an exercise price of \$0.60 per share

The "September 2011 Warrants"

In connection with the sale of the September 2011 Note, we issued the September 2011 Warrant to purchase certain securities of the Company in the Target Transaction Financing (Note 7).

The September 2011 Warrant may be exercised immediately and expires five years after the date of issue. The September 2011 Warrant has an initial exercise price of the lower of \$1.80 and 120% of the per share price in the Target Transaction Financing. The September 2011 Warrant entitles the holder to purchase the number of shares of common stock and/or other securities, including units of securities, sold in the PIPE Offering (as defined in the Warrant) equal to the principal amount of the note issued pursuant to the Securities Purchase Agreement, divided by the lower of \$1.50 and the per share price in the PIPE Offering. The September 2011 Warrant is exercisable in cash or, while a registration statement covering the resale of the underlying shares of common stock and/or other securities issuable upon exercise of the September 2011 Warrant, or an exemption from registration, is not available, by way of a "cashless exercise". The exercise price of the September 2011 Warrant is subject to a "ratchet" anti-dilution adjustment for a period of one year from the issue date of the September 2011 Warrant. 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 September 2011 Warrant shall be immediately reduced to equal the price at which the Company issued the securities.

On November 30, 2011, the holder of the September 2011 Note converted the entire principal amount and accrued interest due with respect to the note into 1,018,356 shares of our common stock and the September 2011 Warrant was cancelled. In exchange, we issued to the holder a Replacement Warrant to purchase 500,000 shares of our common stock at an exercise price of \$1.00 per share.

On June 28, 2012, the holder of the Replacement Warrant exercised his right to acquire 500,000 shares of our common stock through the cashless exercise feature and we issued to the holder 375,000 shares of our common stock.

The "January 2012 Warrants"

On January 11, 2012 and January 25, 2012, we sold an aggregate of 1,300,000 units (the "Units") to accredited investors. Each Unit was sold for a purchase price of \$0.50 per Unit and consisted of: (i) one share of the Company's common stock and (ii) a four-year warrant to purchase 0.5 shares of common stock at an exercise price of \$1.00 per share, subject to adjustment upon the occurrence of certain events (the "January 2012 Warrants"). The January 2012 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 resale of the underlying shares of common stock issuable upon exercise of the warrant. The January 2012 warrants provide the holder with "piggyback registration rights", which obligate us to register the common shares underlying the warrants upon request of the holders in the event that we decide to register any of our common stock either for our own account or the account of a security holder (subject to certain exceptions). Based on authoritative guidance, we have accounted for the January 2012 Warrants as liabilities.

As of September 30, 2012, a total of 650,000 January 2012 Warrants remain outstanding, with an exercise price of \$0.50 per share.

The "February 2012 Warrants"

In connection with the sale of the February 2012 Notes, we issued the February 2012 Warrants entitling the holders to purchase up to 11,500,000 shares of our common stock (Note 7).

The February 2012 Warrants expire ten years from date of issuance and have an exercise price of \$0.40 per common share. The February 2012 Warrants contain a "cashless exercise" feature and provide the holder with "piggyback registration rights", which obligate us to register the common shares underlying the February 2011 Warrants upon request of the holder in the event that we decide to register any of our common stock either for our own account or the account of a security holder (subject to certain exceptions). Based on authoritative guidance, we have accounted for the February 2012 Warrants as liabilities. The liability for the warrants, measured at fair value, based on a Black-Scholes option pricing model, has been offset by a reduction in the carrying value of the related February 2012 Notes.

On April 25, 2012, certain holders February 2012 Warrants exercised their right to acquire 3,500,000 shares of our common stock through the cashless exercise feature and we issued to the holders a total of 2,636,804 shares of our common stock.

On July 3, 2012, the remaining holder of February 2012 Warrants exercised its right to acquire 8,500,000 shares of our common stock through the cashless exercise feature and we issued to the holder 7,650,000 shares of our common stock.

The Advisory and Consulting Warrants

As part of an Advisory and Consulting Agreement between the Company and Tekesta Capital Partners, in April 2012, we issued 200,000 warrants to purchase the Company's common stock. Based on authoritative guidance, we have accounted for these warrants as liabilities.

The warrants issued under the Advisory and Consulting Agreement expire five years from the date of issuance, have an exercise price of \$0.60 per common share and contain a "cashless exercise" feature.

On August 2, 2012, holders of all the outstanding warrants issued under the Advisory and Consulting Agreement exercised their warrants on a cashless basis and received a total of 170,000 shares of the Company's common stock.

"The June 2012 Warrants"

In connection with the issuance of the June 2012 Notes, we issued the June 2012 Warrants entitling the holders to purchase up to a total of 2,250,000 shares of our common stock (Note 7).

The June 2012 Warrants expire ten years from the date of issuance and have an exercise price of \$0.40 per common share. The June 2012 Warrants contain a "cashless exercise" feature. These warrants provide the holder with "piggyback registration rights", which obligate us to register the common shares underlying the warrants upon the request of the holder in the event that we decide to register any of our common stock either for our own account or the account of a security holder (subject to certain exceptions). Based on authoritative guidance, we have accounted for the June 2012 Warrants as liabilities. The liability for the June 2012 Warrants, measured at fair value, based on a Black-Scholes option pricing model, has been offset by a reduction in the carrying value of the related June 2012 Notes.

On June 28, 2012, the holders of the June 2012 Warrants exercised their rights to acquire 2,250,000 shares of our common stock through the cashless exercise feature and we issued to the holders a total of 2,025,000 shares of our common stock.

10. Concentrations. Two customers accounted for approximately 26% and 25% of our sales during the nine months ended September 30, 2012 as compared to 17% and 11% of the our sales for the nine months ended September 30, 2011. Two customers accounted for approximately 37% and 27% of our sales for the three months ended September 30, 2012 as compared to 20% and 9% of our sales for the three months ended September 30, 2011.

#### 11. 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 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).

On January 30, 2012, Mr. Fisher was removed from his position as Executive Vice President for cause.

On February 3, 2012, Mr. Fisher resigned from his position as a director of the Company.

#### 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 period of each lease. Total rent and related expenses under operating leases were \$450,877 and \$474,610 for the nine months ended September 30, 2012 and 2011, respectively, and \$133,595 and \$137,281 for the three months ended September 30, 2012 and 2011, respectively. Operating lease obligations after 2012 relate primarily to office facilities.

#### Litigation

Except as set forth below, we are not involved in any pending legal proceeding or litigation that could have a material impact upon our business or results of operations. To the best of our knowledge, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject, which would reasonably be likely to have a material adverse effect on 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 commenced on March 19, 2012 against BioZone Labs, the Company and a former officer and director of the Company, Daniel Fisher in the United States District Court for the District of Maryland. The plaintiff alleges breach of contract and other commercial wrongdoing and seeks damages 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. We are unable to provide an estimate of the amount or range of reasonable possible losses from this litigation because, among other reasons, the complaint does not set forth a monetary demand.

Daniel Fisher v. BioZone Pharmaceuticals, Inc., Elliot Maza, Brauser Honig Frost Group, Michael Brauser, Barry Honig, and The Frost Group LLC

United States District Court, Northern District of California, No. 12-03716

On July 16, 2012, Daniel Fisher ("Fisher"), a former officer and director of the Company, commenced an action in the United States District Court for the Northern District of California against certain the Company and certain officers and investors thereof. Fisher asserts claims for breach of contract, conversion, wrongful termination, and unjust enrichment, and violation of the federal whistleblower statute arising from his former role as an officer and director of the Company and certain contractual agreements that he entered into with the Company. Fisher seeks \$23 million in damages as against all defendants.

The Company disputes Fisher's allegations, intends to vigorously defend them and has filed an action against Fisher in New York described below. We are unable to provide an estimate of the amount or range of reasonable possible losses from this litigation because it is at a very early stage.

BioZone Pharmaceuticals, Inc. v. Daniel Fisher and 580 Garcia Properties, LLC

Supreme Court of the State of New York, County of New York, No. 652489/2012

On July 18, 2012, the Company commenced an action in New York State Court against Fisher and 580 Garcia Properties, LLC alleging breach of contract, breach of fiduciary duty, negligence, and fraud claims arising from Fisher's former role as an officer and director of the Company. The Company is seeking a minimum of \$2 million in damages, together with the cancellation of 6.65 million shares of the Company's stock, and Fisher's forfeiture of property located at 580 Garcia Avenue, Pittsburg, CA, which property is used by the Company as a warehouse facility.

#### 12. Capital Deficiency

On January 11, 2012 and January 25, 2012, the Company sold an aggregate of 1,300,000 Units to accredited investors. 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 0.5 share of Common Stock purchased at an exercise price of \$1.00 per share, subject to adjustment upon the occurrence of certain events.

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 7 – 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 April 25, 2012, the Company issued 2,636,804 shares of common stock upon the cashless exercise of warrants to purchase 3,000,000 shares.

On June 28, 2012, the Company issued 2,400,000 shares of common stock upon the cashless exercise of warrants to purchase 2,750,000 shares.

On July3, 2012, the Company issued 7,650,000 shares of common stock upon the cashless exercise of warrants to purchase 8,500,000 shares.

On September 28, 2012 the Company cancelled 6,650,000 shares of common stock which were previously issued to Dr. Nian Wu in connection with the acquisition of certain patent rights for Biozone Laboratories, Inc. As consideration for the cancellation, Mr. Wu agreed to the cancellation of a license agreement between Mr. Wu and the Company.

**13. Income Taxes.** No provision for income taxes has been recorded due to the 100% valuation allowance provided against net operating loss carry forwards.

#### 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

|  | <b>December 31, 2011</b> |               | Dece     | mber 31, 2010       |
|--|--------------------------|---------------|----------|---------------------|
| ASSETS   |                          |               |          |                     |
| Command acceptant  |                          |               |          |                     |
| Current assets:  Cash and cash equivalents   | \$                       | 416,333       | \$       | 251 475             |
| *  | Э                        | 410,333       | <b>3</b> | 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              |
| Total current assets   |                          | 2,904,436     |          | 4,193,281           |
|  |                          | 2 2 4 2 4 4 5 |          | 2.262.122           |
| 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  |                          | 4,642,200     |          | 42,677<br>3,340,173 |
|  |                          | 4,042,200     |          | 3,340,173           |
| Total Assets   | \$                       | 7,546,636     | \$       | 7,533,454           |
| LIABILITIES AND SHAREHOLDERS' DEFICIENCY   |                          |               |          |                     |
| Current liabilities:   |                          |               |          |                     |
| 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             |
| Total current liabilities  |                          | 7,278,170     |          | 5,078,580           |
| Long Term Debt   |                          | 3,037,591     |          | 3,044,074           |
| Shareholders' deficiency   |                          |               |          |                     |
| Common stock, \$.001 par value, 100,000,000 shares authorized, 55,181,165 and 21,000,000 shares issued and outstanding at December 31, 2011, and 2010, |                          |               |          |                     |
| respectively   |                          | 55,181        |          | 21,000              |
| Additional paid-in capital   |                          | 3,339,171     |          | 95,967              |
| Accumulated deficit  |                          | (6,163,477)   |          | (706,167)           |
| Total shareholders' deficiency   |                          | (2,769,125)   |          | (589,200)           |
| Total liabilities and shareholders' deficiency   | \$                       | 7,546,636     | \$       | 7,533,454           |
|  |                          |               |          |                     |

# BIOZONE PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

|   |           | Year Ended December 31, |    |                      |  |
|---|-----------|-------------------------|----|----------------------|--|
|   | _         | 2011                    |    | 2010                 |  |
| Sales   | \$        | 12,605,146              | \$ | 15,253,685           |  |
| Cost of sales   |           | (8,639,658)             |    | (8,427,608)          |  |
| Gross profit  |           | 3,965,488               |    | 6,826,077            |  |
| Operating Expenses: General and adminstrative expenses  |           | 7 152 961               |    | 6 617 240            |  |
| Research and development expenses   |           | 7,452,864<br>399,624    |    | 6,617,249<br>240,873 |  |
| Total operating expenses  |           | 7,852,488               |    | 6,858,122            |  |
| Loss from operations  |           | (3,887,000)             |    | (32,045)             |  |
| Interest expense  |           | (1,242,853)             |    | (439,018)            |  |
| Change in fair value of derivative liability Equity in earnings (loss) of unconsolidated subsidiary |           | (281,508)<br>(42,677)   |    | 55,305               |  |
| Loss before credit for income taxes   |           | (5,454,038)             |    | (415,758)            |  |
| Provision (benefit) for income taxes  |           | 3,272                   |    | (95,945)             |  |
| Net loss  | \$        | (5,457,310)             | \$ | (319,813)            |  |
| Net loss per common share   | <u>\$</u> | (0.12)                  | \$ | (0.02)               |  |
| Basic and diluted weighted average common shares outstanding  | <u> </u>  | 44,552,409              |    | 21,000,000           |  |
| F-20  |           |                         |    |                      |  |

# BIOZONE PHARMACEUTICALS INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

|   | Year Ended December        |           |  |
|---|----------------------------|-----------|--|
|   | 2011                       | 2010      |  |
|   |                            |           |  |
| Cash flows from operating activities  | ф. (5.45 <b>7.21</b> 0). ф | (210.012) |  |
| Net (loss)  | \$ (5,457,310) \$          | (319,813) |  |
| Adjustments to reconcile net (loss) to net cash used in operating activities: | 2.25                       |           |  |
| Deferred income taxes   | 3,272                      | 554040    |  |
| 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   | (420,953)                  | (261,420) |  |
| Cash flows from investing activities  |                            |           |  |
| Purchase of property and equipment  | (575,430)                  | (357,610) |  |
| Cash acquired on business combination   | 585,720                    | (337,010) |  |
| Net cash provided by (used in) investing activities                           | 10,290                     | (357,610) |  |
|   |                            |           |  |
| 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                                     | 575,521                    | 283,098   |  |
| Net increase (decrease) in cash and cash equivalents                          | 164,858                    | (335,932) |  |
| Cash and cash equivalents, beginning of year                                  | 251,475                    | 587,407   |  |
| cush and cush equitations, segunning of year                                  |                            | 201,101   |  |
| Cash and cash equivalents, end of year  | \$ 416,333 \$              | 251,475   |  |
| Supplemental disclosures of cash flow information:                            |                            |           |  |
| Interest paid   | \$ 539,616 \$              | 439,018   |  |
| Conversion of convertible note payable and accrued interest to common stock   | \$ 509,178 \$              |           |  |

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

|  | Common Stock        |    |          |                            |                     |                |
|--|---------------------|----|----------|----------------------------|---------------------|----------------|
|  | Number of<br>Shares | A  | mount    | Additional paid in capital | Accumulated defecit | Total          |
| Balance as of December 31, 2009                                    | 21,000,000          | \$ | 21,000   | \$ 138,998                 | \$ (386,354)        | \$ (226,356)   |
| Distribution   |                     |    |          | (43,031)                   |                     | (43,031)       |
| Net loss for year  |                     |    |          |                            | (319,813)           | (319,813)      |
| Balance at December 31, 2010                                       | 21,000,000          |    | 21,000   | 95,967                     | (706,167)           | 589,200        |
| Effect of reverse merger   | 46,029,396          |    | 46,029   | 1,953,971                  |                     | 2,000,000      |
| Shares issued to consultant  | 500,000             |    | 500      | 1,949,500                  |                     | 1,950,000      |
| Shares issued for liquidated damages                               | 13,914              |    | 14       | 6,943                      |                     | 6,957          |
| 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 cancelled to consultant                                     | (500,000)           |    | (500)    | (1,949,500)                |                     | (1,950,000)    |
| Cancellation of ISR shares   | (13,948,000)        |    | (13,948) | 13,948                     |                     |                |
| Net loss for the year  |                     |    |          |                            | (5,457,310)         | (5,457,310)    |
| Balance at December 31, 2011                                       | 55,181,165          | \$ | 55,181   | \$ 3,339,171               | \$ (6,163,477)      | \$ (2,769,125) |
|  | F-22                |    |          |                            |                     |                |

#### 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 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 Laboratories, LLC ("BetaZone") in exchange for 321,101 shares of our common stock, for a total of 21 million shares. 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. We have 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 historical financial statements of the BioZone Lab Group, and BioZone Pharmaceuticals, Inc. from the date of acquisition. As a result of the June 30, 2011 transaction referred to above, we recorded the fair value of the acquisition at \$2,000,000 as further described below. In addition, on September 21, 2011, the Company issued 13,914 shares of common stock to certain shareholders in consideration for the delay in filing the Company's Registration Statement on Form S-1, as required in the Asset Purchase Agreement. These shares were valued at \$0.50 per share and the resulting amount was charged to interest expense at the time of issuance.

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

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 | (5,515,081) (516,458)                     |
|                          |   |
| Net loss per share       | <u>\$ (0.12)</u> <u>\$ (0.02)</u>         |

The Consolidated Statements of Operations for the Year Ended December 31, 2011 and December 31, 2010 contains a revised presentation of Net loss per common share and Basic and diluted weighted average common shares outstanding for each period presented as compared to such amounts included on Form 10-K for the period ended December 31, 2011 filed on April 16, 2012. The following table describes the revisions:

| Consolidated Statement of Operations   | Year ended<br>December 31, 2011 | Year ended<br>December 31, 2010 |
|--|---------------------------------|---------------------------------|
| Net loss per common share - originally reported                                    | (0.11)                          | (0.01)                          |
| Basic and diluted weighted average common shares outstanding - originally reported | 50,443,025                      | 44,749,999                      |
| Net loss per common share - adjsuted   | (0.12)                          | (0.02)                          |
| Basic and diluted weighted average common shares outstanding - adjusted            | 44,552,409                      | 21,000,000                      |

Also, the Consolidated Statements of Changes in Shareholders' Deficiency through the year ended December 31, 2011 contains a revised presentation of changes in shareholders' deficiency throughout the periods presented as compared to such changes included on Form 10-K for the period ended December 31, 2011 filed on April 16, 2012. The following table describes the revisions:

### As originally reported on form 10-K

|  | _                | Common Stock  |                                  |                       |                |
|--|------------------|---------------|----------------------------------|-----------------------|----------------|
|  | Number of Shares | <u>Amount</u> | Additional<br>paid in<br>capital | Shareholder's defecit | <u>Total</u>   |
| 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                                       | 44,749,999       | 44,750        | 72,217                           | (706,167)             | (589,200)      |
| 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                                       | 55,181,165       | \$ 55,181     | \$ 3,339,171                     | \$ (6,163,477)        | \$ (2,769,125) |
| As revised on the accompanying financial statements                |                  |               |                                  |                       |                |

### As revised on the accompanying financial statements

|  | <u>.</u>         | Common Stock  | <u>Additional</u>                |                       |              |
|--|------------------|---------------|----------------------------------|-----------------------|--------------|
|  | Number of Shares | <u>Amount</u> | <u>paid in</u><br><u>capital</u> | Shareholder's defecit | <u>Total</u> |
| Balance as of December 31, 2009                                    | 21,000,000       | \$ 21,000     | \$ 138,998                       | \$ (386,354) \$       | (226,356)    |
| Distribution   |                  |               | (43,031)                         |                       | (43,031)     |
| Net loss for year  |                  |               |                                  | (319,813)             | (319,813)    |
| Balance at December 31, 2010                                       | 21,000,000       | 21,000        | 95,967                           | (706,167)             | (589,200)    |
| Effect of reverse merger   | 46,029,396       | 46,029        | 1,953,971                        |                       | 2,000,000    |
| Shares issued to consultant  | 500,000          | 500           | 1,949,500                        |                       | 1,950,000    |
| Shares issued for liquidated damages                               | 13,914           | 14            | 6,943                            |                       | 6,957        |
| 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 cancelled to consultant                                     | (500,000)        | (500)         | (1,949,500)                      |                       | (1,950,000)  |
| Cancellation of ISR shares   | (13,948,000)     | (13,948)      | 13,948                           |                       | -            |
| Net loss for the year  |                  |               |                                  | (5,457,310)           | (5,457,310)  |
| Balance at December 31, 2011                                       | 55,181,166       | \$ 55,181     | \$ 3,339,171                     | \$ (6,163,477)        | (2,769,125)  |

The revised presentation in the Consolidated Statements of Operations and Consolidated Statements of Changes in Shareholders' Deficiency arises from a revision of the number of shares outstanding as of December 31, 2009, the first date of the Company's financial statements included in this Amendment No. 8 to Form S-1. Specifically, we reduced the number of shares outstanding as of December 31, 2009 from 44,749,999 to 21,000,000 to accurately reflect the number of shares issued to the owners of the BioZone Labs Group, the accounting acquiror in the reverse merger. As a result of this change, we revised the Consolidated Balance Sheets as of December 31, 2011 and 2010 to show as 21,000,000 the number of shares of common stock issued and outstanding at December 31, 2010.

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

Basis of Consolidation

The consolidated financial statements include the accounts of Biozone Phamaceuticals, 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 - 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     | <b>December 31, 2011</b> | <b>December 31, 2010</b> |
|--------------------------|-----------------|--------------------------|--------------------------|
| 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                  |
|                          |                 | 7,900,649                | 7,329,317                |
| Accumulated depreciation |                 | (4,558,202)              | (4,067,184)              |
| Net                      |                 | 3,342,447                | 3,262,133                |

# **NOTE 4 – 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 Invesment in Betazone Laboratories, LLC assuming 100% ownership interest is as follows:

|                         | 2011      | 2010    |
|-------------------------|-----------|---------|
| Balance sheet           |           |         |
| Current assets          | 124,462   | 95,054  |
| Current Liabilities     | 131,672   | 217     |
|                         |           |         |
| Statement of operations |           |         |
| 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 5 – 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"). 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.

# $NOTE\ 6-Notes\ Payable-Shareholder$

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 7 - Long Term Debt

|   | Year ended D    | )ece | mber 31,  |
|---|-----------------|------|-----------|
| Notes payable of Biozone Labs   | 2011            |      | 2010      |
| 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   | \$<br>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   |
| Notes payable of 580 Garcia Properties  |                 |      |           |
| 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 |
|   |                 |      |           |
|   | \$<br>3,298,332 | \$   | 3,321,373 |
| Less: current portion   | 260,741         |      | 277,299   |
|   | 3,037,591       |      | 3,044,074 |
|   |                 |      |           |
| 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  |                 |      | _         |

# NOTE 8 – Warrants

Thereafter

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 9 – 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)           | 0.6%                    | -12.0% |

The benefit for income tax is summarized as follows:

|                                | Year ended December 31, |           |                |
|--------------------------------|-------------------------|-----------|----------------|
|                                |                         | 2011      | 2010           |
| Federal:                       |                         |           |                |
| Current                        | \$                      | _         | \$<br>         |
| Deferred                       | (1                      | ,693,454) | (81,553)       |
| State and local:               |                         |           |                |
| Current                        |                         | _         |                |
| Deferred                       |                         | (298,845) | (14,392)       |
| Change in valuation allowance  |                         | 1,995,571 | <br><u> </u>   |
| Income tax provision (benefit) | \$                      | 3,272     | \$<br>(95,945) |

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        |
| Deferred tax assets             |                         |             |
| Net operating losses            | \$ 1,003,188            | \$ 274,138  |
| Allowance for doubtful accounts | 179,810                 | 47,342      |
|                                 | 1,182,998               | 321,480     |
| Less: valuation allowance       | (1,182,998)             | (274,138)   |
|                                 |                         | 47,342      |
| Deferred tax liability          |                         |             |
| Depreciation                    | 102,022                 | (146,092)   |
| Total deferred tax liability    | \$ 102,022              | \$ (98,750) |

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 10 - 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 11 – 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       | \$<br>466,414   |
|------------|-----------------|
| 2013       | 442,623         |
| 2014       | 442,623         |
| 2015       | 211,022         |
| 2016       | 63,481          |
| Thereafter | _               |
|            | \$<br>1,626,163 |

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.

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 commenced on March 19, 2012 against BioZone Labs, the Company and a former officer and director of the Company, Daniel Fisher in the United States District Court for the District of Maryland. The plaintiff alleges breach of contract and other commercial wrongdoing and seeks damages 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. We are unable to provide an estimate of the amount or range of reasonable possible losses from this litigation because, among other reasons, the complaint does not set forth a monetary demand.

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 Therepeutics, 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 12 - 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 party, 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.

# BIOZONE PHARMECEUTICALS, INC.

8,345,310 Shares

**Common Stock** 

**PROSPECTUS** 

, 2013

# PART II - INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 13. Other Expenses of Issuances and Distribution.

The following table sets forth the costs and expenses payable by us in connection with the issuance and distribution of the securities being registered. None of the following expenses are payable by the selling stockholder. All of the amounts shown are estimates, except for the SEC registration fee.

| SEC registration fee         | \$<br>3,953.07  |
|------------------------------|-----------------|
| Legal fees and expenses      | \$<br>50,000    |
| Accounting fees and expenses | \$<br>25,000    |
| Miscellaneous                | \$<br>15,000    |
|                              |                 |
| TOTAL                        | \$<br>93,953.07 |

#### Item 14. Indemnification of Directors and Officers.

Nevada Revised Statutes ("NRS") Sections 78.7502 and 78.751 provide us with the power to indemnify any of our directors and officers. The director or officer must have conducted himself/herself in good faith and reasonably believe that his/her conduct was in, or not opposed to, our best interests. In a criminal action, the director, officer, employee or agent must not have had reasonable cause to believe his/her conduct was unlawful.

Under NRS Section 78.751, advances for expenses may be made by agreement if the director or officer affirms in writing that he/she believes he/she has met the standards and will personally repay the expenses if it is determined such officer or director did not meet the standards

Our Bylaws include an indemnification provision under which we have the power to indemnify our directors, officers, former directors and officers, or any person who serves or served at our request for our benefit as a director or officer of another corporation or our representative in a partnership, joint venture, trust, or other enterprise (including heirs and personal representatives) against all expenses, liability, and loss actually and reasonably incurred.

We also have a director and officer indemnification agreement with our Chairman that provides, among other things, for the indemnification to the fullest extent permitted or required by Nevada law, provided that such indemnity shall not be entitled to indemnification in connection with any "claim" (as such term is defined in the agreement) initiated by the indemnity against us or our directors or officers unless we join or consent to the initiation of such claim, or the purchase and sale of securities by the indemnity in violation of Section 16(b) of the Exchange Act.

Any repeal or modification of these provisions approved by our stockholders shall be prospective only, and shall not adversely affect any limitation on the liability of any of our directors or officers existing as of the time of such repeal or modification.

We are also permitted to apply for insurance on behalf of any director, officer, employee or other agent for liability arising out of his actions, whether or not the NRS would permit indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Our Amended and Restated Articles of Incorporation provides a limitation of liability such that no director or officer shall be personally liable to us or any of our stockholders for damages for breach of fiduciary duty as a director or officer, involving any act or omission of any such director or officer, provided there was no intentional misconduct, fraud or a knowing violation of the law, or payment of dividends in violation of NRS Section 78.300

# Item 15. Recent Sales of Unregistered Securities.

On August 2, 2012, holders of all the outstanding warrants issued under the Advisory and Consulting agreement exercised their warrants on a cashless basis and received a total of 170,000 shares of the Company's common stock. The shares were issued to "accredited investors," as such term is defined in the Securities Act, and were offered and sold in reliance upon the exemption from registration afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws.

On July 3, 2012, the remaining holder of February 2012 Warrants exercised its right to acquire 8,500,000 shares of our common stock through the cashless exercise feature and we issued to the holder 7,650,000 shares of our common stock. The shares were issued to "accredited investors," as such term is defined in the Securities Act, and were offered and sold in reliance upon the exemption from registration afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws.

On June 28, 2012, we issued \$455,274 of our 10% convertible promissory notes and warrants to purchase an aggregate of 2,250,000 shares of our Common Stock at an exercise price of \$0.40 per share to certain accredited investors in consideration for the cancellation of certain of our outstanding promissory notes, in the aggregate principal amount of \$450,000 and accrued interest of \$5,274, issued on June 13, 2012 and April 18, 2012, to such prior investors. The notes were issued to "accredited investors," as such term is defined in the Securities Act and were offered and sold in reliance on the exemption from registration afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws.

On June 13, 2012, we sold 10% promissory notes to accredited investors for an aggregate purchase price of \$200,000. The principal amount of the notes is payable in cash on the date that is the earlier of receipt by the Company of \$500,000 or more from any source (other than sales in the ordinary course of business) or three months from the issuance date. The notes were issued to "accredited investors," as such term is defined in the Securities Act and were offered and sold in reliance on the exemption from registration afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws.

On April 18, 2012, we sold a 10% senior secured convertible promissory note to an accredited investor for a purchase price of \$250,000. 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"). August 7, 2012, the last date of such scheduled payment, is 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, is 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 thereunder or (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. 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 13, 2012, we sold a 10% senior convertible promissory note to an accredited 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"). July 7, 2012, the last date of such scheduled payment, is 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, we issued 455,000 shares of its common stock to certain individuals who had previously purchased shares 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 with Opko Health, Inc., pursuant to which we sold (i) a \$1,700,000 10% secured convertible promissory note due two years from the date of issuance and (ii) ten year warrants to purchase 8,500,000 shares of our common stock at an exercise price of \$0.40 per share for gross proceeds to us of \$1,700,000. The warrants may be exercised on a cashless basis commencing on the issue date. Dr. Philip Frost, the trustee of the Frost Gamma Investments Trust, a holder of 6.07% of our issued and outstanding common stock, is the Chairman and Chief Executive Officer of Opko Health, Inc. On February 28, 2012 and February 29, 2012, we sold an additional \$600,000 of notes and issued warrants on the same terms to purchase an additional 3,000,000 shares of our common stock to additional buyers for gross proceeds to us of \$600,000. 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, we issued four year warrants to purchase 1,000,000 shares of our 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 January 25, 2012, we sold an aggregate of 700,000 units of our securities for gross proceeds 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 warrants may be exercised on a cashless basis after twelve 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. We 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 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 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 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 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 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 upon conversion of the principal and all of the interest due on a certain convertible promissory note issued on September 22, 2011. We also issued the holder a five year 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 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 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 five year 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"). The warrant has an exercise price equal to the lower of (x) \$1.80 or (y) 120% of the price that the Company's securities will be sold in a Target Transaction Financing. 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 July 7, 2011, we issued 500,000 shares of our common stock to a consultant in exchange for strategic corporate advisory services. 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 June 30, 2011, we issued an aggregate of (i) 19,266,055 shares of our common stock to the shareholders of BioZone Labs in consideration for 100% of the issued and outstanding shares of common stock of BioZone Labs; (ii) 1,027,523 shares of our common stock to the members of Equalan in consideration for 100% of the outstanding membership interests of Equalan; (iii) 385,321 shares of our common stock to the members of Equachem in consideration for 100% of the outstanding membership interests of Equachem; and 321,101 shares of our common stock to the members of BetaZone in consideration for 45% of the outstanding membership interests of BetaZone. 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 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) and five year 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 warrants have an exercise price of 120% of the price that the Company's securities will be sold in a Target Transaction. 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 and Rule 506 promulgated thereunder. In March 2012, we 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.

On March 1, 2011, we issued 1,000,000 shares of our common stock to Roberto Prego-Novo Jr., the adult son of our Chairman, in consideration for \$30,000. 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 by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

In June 2007 we issued 529,800 shares of our common stock for \$0.25 per share for gross proceeds of \$132,450. In March 2007, we issued 240,000 shares of our common stock to repay certain loans in the amount of \$60,000. The shares were issued were issued in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act and Rule 506 promulgated thereunder.

#### Item 16. Exhibits and Financial Statement Schedules.

#### (a) Exhibits.

The exhibits to the registration statement are listed in the Exhibit Index to this registration statement and are incorporated by reference herein.

(b) Financial Statement Schedules.

All financial statement schedules have been omitted, since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and notes thereto.

# Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;
- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement on Form S-1/A to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Englewood Cliffs, State of New Jersey, on the 13<sup>th</sup> day of February 2013.

# BIOZONE PHARMECEUTICALS, INC.

(Registrant)

**SIGNATURE** 

By: /s/ Elliot Maza

Name: Elliot Maza

Title: Chief Executive Officer and Chief Financial Officer (Principal Executive Officer and Principal Financial and

DATE

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.

TITLE

/s/ Elliot Maza

Elliot Maza

Chief Executive Officer and Chief Financial Officer

\*

Roberto Prego-Novo

Chairman of the Board of Directors

February 13, 2013

\*

Brian Keller

President, Chief Scientific Officer and Director

February 13, 2013

<sup>\*</sup> Executed on February 13, 2013 by Elliot Maza as attorney-in-fact under power of attorney granted in the Registration Statement previously filed on September 21, 2011.

# EXHIBIT INDEX

| Exhibit No. | Description  |
|-------------|--|
| 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)   |
| 5.1         | Opinion of Sichenzia Ross Friedman Ference LLP (previously filed)  |
| 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        | Form of Securities Purchase Agreement, dated as of February 28, 2011. (18)   |
| 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        | Form of 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 dated June 30, 2011 (Equalan LLC) (5)   |
| 10.13       | Form of Stock Purchase Agreement dated June 30, 2011 (BioZone Laboratories Inc.) (5)   |
| 10.14       | Form of LLC Membership Interest Purchase Agreement dated June 30, 2011 (Equachem LLC) (5)  |
| 10.15       | Form of LLC Membership Interest Purchase Agreement dated June 30, 2011 (Betazone LLC) (5)  |
| 10.16       | Form of Lockup Agreement (5)   |
| 10.17       | Stock Option Agreement, dated June 30, 2011, between Brian Keller and Opko Health, Inc. (5)  |
| 10.18       | Stock Option Agreement, dated June 30, 2011, between Daniel Fisher and Opko Health, Inc. (5)   |
| 10.19       | Employment Agreement, dated June, 2011, between the Company and Brian Keller (5)   |
| 10.20       | Employment Agreement, dated June 30, 2011, between the Company and Daniel Fisher (5)   |
| 10.21       | Employment Agreement, dated June 30, 2011, between the Company and Christian Oertle (5)  |
| 10.22       | License Agreement, dated November 7, 2006, between BioZone Laboratories Inc. and BetaZone Laboratories LLC (5)                               |
| 10.23       | Amendment No. 1 to License Agreement, dated April 4, 2011, between BioZone Laboratories Inc. and BetaZone Laboratories LLC (5)               |
| 10.24       | Amendment No. 2 to License Agreement, dated June 29, 2011, between BioZone Laboratories Inc. and BetaZone Laboratories LLC (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 (11)   |
| 10.33   | Form of Warrant (11)  |
| 10.34   | Form of Subscription Agreement (12)   |
| 10.35   | Form of Warrant (12)  |
| 10.36   | Form of Security and Stock Pledge Agreement (12)  |
| 10.37   | Form of Note (13)   |
| 10.38   | Form of Note (14)   |
| 10.39   | Stock Purchase Agreement, dated December 29, 2011, by and among the Company, Global Property Corp. and ISR Investments LLC, Eduardo Biancardi and Timothy Neely, (15) |
| 10.40   | Qusome Patent Assignment from Brian Charles Keller et al. to the Company, dated December 19, 2006 (15)  |
| 10.41   | License Agreement, dated February 13, 2012, between the Company and Nian Wu, (15)   |
| 10.42   | Assignment of Patent Rights, dated February 12, 2012, between the Company and Nian Wu and Brian Charles Keller(15)  |
| 10.43   | Lease, dated March 1, 2004, between the Company and 580 Garcia Properties LLC (15)  |
| 10.44   | Distribution Agreement, dated February 24, 2012, between the Company and OPKO Pharmaceuticals, LLC (15)   |
| 10.45   | Limited License Agreement, dated February 24, 2012, between the BioZone Laboratories, Inc., Equachem, LLC, the Company and OPKO Pharmaceuticals, LLC (15)             |
| 10.46** | Supply Agreement (redacted)(19)   |
| 10.47   | Form of LLC Membership Interest Purchase Agreement with exhibits dated June, 2011 (Equalan LLC) (15)  |
| 10.48   | Form of Stock Purchase Agreement (BioZone Laboratories Inc.) with exhibits dated June, 2011 (15)  |
| 10.49   | Form of LLC Membership Interest Purchase Agreement (Equachem LLC) with exhibits dated June, 2011 (15)   |
| 10.50   | Form of LLC Membership Interest Purchase Agreement (Betazone LLC) with exhibits dated June, 2011 (15)   |
| 10.51   | Promissory Note issued to Daniel Fisher dated September 10, 2001 (15)   |
| 10.52   | Promissory Note issued to Daniel Fisher dated September 1, 2002 (15)  |
| 10.53   | Promissory Note issued to Daniel and Sharon Fisher dated September 30, 2005 (15)  |
| 10.54   | Promissory Note issued to Daniel Fisher dated December 31, 2008 (15)  |
| 10.55   | Promissory Note issued to Daniel and Sharon Fisher dated January 7, 2010 (15)   |
| 10.56   | Promissory Note issued to Daniel and Sharon Fisher dated April 8, 2010 (15)   |
| 10.57   | Promissory Note issued to Daniel and Sharon Fisher dated May 19, 2010 (15)  |
| 10.58   | Form of Purchase Order (15)   |
| 10.59   | Amendment No. 2 to Betazone License Agreement, dated June, 2011 between BioZone Laboratories, Inc. and BetaZone Laboratories, LLC, (15)                               |
| 10.60   | Promissory Note issued to General Electric Capital Corporation, dated August 23, 2007, (15)   |
| 10.61   | Form of Promissory Note (16)  |

| 10.62   | Form of Warrant (16)   |  |
|---|--|--|
| 10.63   | Separation and Release Agreement between the Company and Nian Wu, dated September, 2012. (17)                |  |
| 10.64   | License Agreement between the Company and Nian Wu, dated September 20, 2012. (17)                            |  |
| 10.65   | Lease Agreement, dated May 22, 2006, between BioZone Laboratories, Inc. and Empire Business Park . (18)      |  |
| 21  | List of Subsidiaries (4)   |  |
| 23.1  | Consent of Paritz & Company PA*  |  |
| 23.2  | Consent of Sichenzia Ross Friedman Ference LLP (included in Exhibit 5.1) (previously filed)                  |  |
| 24.1  | Power of Attorney (10)   |  |
| * Filed herewith  |  |  |
| ** Confidential tre   | eatment has been requested for this exhibit and confidential portions have been filed with the SEC           |  |
| (1) Incorporated by   | y reference to the Company's Registration Statement on Form SB-2, filed with the SEC on September 20, 2007.  |  |
| (2) Incorporated by   | y 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   | y reference to the Company's Current Report on Form 8-K, filed with the SEC on March 1, 2011.                |  |
| (4) Incorporated by   | y 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   | y 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   | y reference to the Company's Current Report on Form 8-K, filed with the SEC on December 7, 2011              |  |
| (10) Included on the  | he signature page hereto   |  |
| (11) Incorporated   | by reference to the Company's Current Report on Form 8-K, filed with the SEC on January 13, 2012             |  |
| (12) Incorporated   | by reference to the Company's Current Report on Form 8-K, filed with the SEC on March 1, 2012                |  |
| (13) Incorporated   | by reference to the Company's Current Report on Form 8-K, filed with the SEC on March 16, 2012               |  |
| (14) Incorporated   | by reference to the Company's Current Report on Form 8-K, filed with the SEC on April 23, 2012               |  |
| (15) Incorporated   | by reference to the Company's Registration Statement on Form S-1/A, filed with the SEC on July 2, 2012       |  |
| (16) Incorporated   | by reference to the Company's Current Report on Form 8-K, filed with the SEC on July 5, 2012                 |  |
| (17) Incorporated   | by reference to the Company's Current Report on Form 8-K filed with the SEC on September 24, 2012            |  |
| (18) Incorporated   | by reference to the Company's Registration Statement on Form S-1/A, filed with the SEC on September 28, 2012 |  |

(19) Incorporated by reference to the Company's Registration Statement on Form S-1/A, filed with the SEC on January 31, 2013

15 Warren Street, Suite 25 Hackensack, NJ 07601 (201) 342-342-7753 Fax: (201) 342-7598 E-mail: paritz@paritz.com

# Paritz & Company, P.A.

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors
BioZone Pharmaceuticals, Inc.
550 Sylvan Avenue, Suite 101
Englewood Cliffs, NJ 07632

Gentlemen:

We consent to the use in this Amendment No. 8 to the Registration Statement on Form S-1 of our report dated April 12, 2012, relating to the consolidated financial statements of BioZone Pharmaceuticals, Inc. for the years ended December 31, 2011 and 2010, which appears in such registration statement.

We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ Paritz and Company P.A.

Paritz & Company, P.A. Hackensack, New Jersey February 13, 2013