

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2012

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

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

Commission File No.: 333-146182

**BioZone Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Nevada**  
(State or other jurisdiction of  
incorporation or organization)

**20-5978559**  
(I.R.S. Employer  
Identification No.)

**550 Sylvan Avenue  
Suite 101  
Englewood Cliffs, NJ 07632**  
(Address of principal executive offices)

Issuer's telephone number: **(201) 608-5101**

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

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

**APPLICABLE ONLY TO CORPORATE ISSUERS**

As of November 14, 2012, there were 63,142,969 shares of our common stock outstanding.

Transitional Small Business Disclosure Format: Yes  No

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**Quarterly Report on Form 10-Q for the  
Nine months ended September 30, 2012  
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**PART 1: FINANCIAL INFORMATION**  
**ITEM 1 – FINANCIAL STATEMENTS**

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

	<u>September 30, 2012</u> (Unaudited)	<u>December 31, 2011</u>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 82,621	\$ 416,333
Account receivable net of allowance for doubtful accounts \$163,339 and \$449,524, respectively	919,503	523,039
Inventories	2,151,779	1,819,751
Prepaid expenses and other current assets	489,663	145,313
<b>Total current assets</b>	<u>3,643,566</u>	<u>2,904,436</u>
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
	<u>4,616,343</u>	<u>4,642,200</u>
<b>Total Assets</b>	<u>\$ 8,259,909</u>	<u>\$ 7,546,636</u>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIENCY</b>		
<b>Current liabilities:</b>		
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
<b>Total current liabilities</b>	<u>5,421,344</u>	<u>7,278,170</u>
<b>Long Term Debt</b>	<u>2,913,492</u>	<u>3,037,591</u>
<b>Shareholders' deficiency</b>		
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	63,143	55,181
Additional paid-in capital	10,484,611	3,339,171
Accumulated deficit	(10,622,681)	(6,163,477)
<b>Total shareholders' deficiency</b>	<u>(74,927)</u>	<u>(2,769,125)</u>
<b>Total liabilities and shareholders' deficiency</b>	<u>\$ 8,259,909</u>	<u>\$ 7,546,636</u>

See accompanying notes to consolidated financial statements

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>
Sales	\$ 4,893,758	\$ 3,930,503	\$ 13,315,944	\$ 8,937,818
Cost of sales	<u>(2,871,266)</u>	<u>(1,845,127)</u>	<u>(7,817,619)</u>	<u>(5,209,891)</u>
Gross profit	<u>2,022,492</u>	<u>2,085,376</u>	<u>5,498,325</u>	<u>3,727,927</u>
<b>Operating Expenses:</b>				
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	<u>155,941</u>	<u>4,011</u>	<u>584,059</u>	<u>119,167</u>
<b>Total Operating Expenses</b>	<u>1,660,174</u>	<u>4,301,668</u>	<u>5,464,702</u>	<u>6,833,633</u>
<b>Income (Loss) from operations</b>	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	
<b>Loss before income taxes</b>	<u>(98,730)</u>	<u>(2,499,703)</u>	<u>(4,459,204)</u>	<u>(3,611,312)</u>
Income taxes	—	—	—	—
Net loss	<u>\$ (98,730)</u>	<u>\$ (2,499,703)</u>	<u>\$ (4,459,204)</u>	<u>\$ (3,611,312)</u>
Net loss per common share	<u>\$ (0.00)</u>	<u>\$ (0.04)</u>	<u>\$ (0.07)</u>	<u>\$ (0.07)</u>
Basic and diluted weighted average common shares outstanding	<u>69,418,903</u>	<u>67,492,714</u>	<u>61,631,047</u>	<u>49,112,016</u>

See accompanying notes to consolidated financial statements

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

	<u>Nine Months Ended September 30,</u>	
	<u>2012</u>	<u>2011</u>
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:		
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	<u>(1,636,699)</u>	<u>(40,986)</u>
Cash flows from investing activities		
Purchase of property and equipment	(320,116)	(157,568)
Cash acquired on business combination		585,720
Net cash used in investing activities	<u>(320,116)</u>	<u>428,152</u>
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	<u>1,623,103</u>	<u>143,084</u>
Net increase (decrease) in cash and cash equivalents	(333,712)	530,250
Cash and cash equivalents, beginning of period	<u>416,333</u>	<u>251,475</u>
Cash and cash equivalents, end of period	<u>\$ 82,621</u>	<u>\$ 781,725</u>
Supplemental disclosures of cash flow information:		
Interest paid	\$ 312,232	\$ 319,872
Debt discount from warrant liability	\$ 2,755,274	\$ —
Cashless exercise of warrants for common stock	<u>\$ 6,503,201</u>	<u>\$ —</u>

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 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 May 16, 2011, we acquired substantially all of the assets and assumed all of the liabilities of Aero Pharmaceuticals, Inc. ("Aero") pursuant to an Asset Purchase Agreement dated as of that date. Aero manufactures, markets and distributes a line of dermatological products under the trade name of Baker Cummins Dermatologicals (see Note 4).

On September 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 BioZone Lab Group, and Aero from the date of acquisition.

These consolidated financial statements are presented on the basis that we will continue as a going concern concept which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. 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.

### 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. Aero Acquisition

On May 16, 2011, we acquired the assets and assumed the liabilities of Aero in exchange for a total of 8,331,396 shares of our common stock, valued at \$2 million as further described below. The acquisition was accounted for under the acquisition method of accounting. On September 21, 2011, the Company issued 13,914 shares of common stock to Aero in consideration for the delay in filing the Company's Registration Statement on Form S-1, as required in the Asset Purchase Agreement between the Company and Aero. 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 of Aero which were identified based on an analysis of the transaction, a review of available supporting documents, and discussions with management. The analysis focused on determining which components met the requirements for recognition as an intangible asset separate from goodwill under ASC 805, and had characteristics that allowed its value to be reasonably estimated. This analysis ultimately identified the acquired brands and customer relationships as the qualifying intangible assets subject to amortization, which were valued at \$110,000 and \$172,800, respectively. Intangible assets recognized apart from goodwill are classified as finite lived (subject to amortization) on the basis of the intangible asset's expected useful life, which was determined to be 5 years.

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

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



**5. 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:

<u>Fixed Asset</u>	<u>Useful Life</u>	<u>September 30, 2012</u>	<u>December 31, 2011</u>
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
		<u>8,215,031</u>	<u>7,900,649</u>
Accumulated depreciation		<u>(4,870,605)</u>	<u>(4,558,202)</u>
Net		<u>3,344,426</u>	<u>3,342,447</u>

**6. 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:

	<u>September 30, 2012</u>	<u>December 31, 2011</u>
<b><u>Balance sheet</u></b>		
Current assets	9,768	124,462
Current liabilities	264,199	131,672
<b><u>Statement of operations</u></b>		
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.

## **7. 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 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 2011 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	<u>(500,000)</u>
	3,255,274
Less debt discount	<u>2,027,531</u>
Balance September 30, 2012	<u><u>1,227,743</u></u>

**8. 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.

**9. Long Term Debt.** Long-term debt consists of:

	<u>9/30/2012</u>	<u>12/31/2011</u>
<b>Notes payable of Biozone Labs</b>		
Capitalized lease obligations bearing interest at rates ranging from 8.6% to 16.3%, payable in monthly installments of \$168 to \$1,589, inclusive of interest	\$ 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
<b>Notes payable of 580 Garcia Properties</b>		
Mortgage payable of 580 Garcia collateralized by the land and building payable in monthly installments of \$20,794, inclusive of interest at 7.24% per annum	2,598,386	2,643,438
	3,107,739	3,298,332
Less: current portion	194,247	260,741
	<u>\$ 2,913,492</u>	<u>\$ 3,037,591</u>

**10. 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.

**11. 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 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.

## **12. Contingencies**

#### *Employment Agreements*

On June 30, 2011, the Company entered into three year executive employment agreements with three stockholders, Brian Keller, Christian Oertle and Daniel Fisher, to serve as our President, Chief Operating Officer and Executive Vice President, respectively. The agreements with Messrs. Keller and Fisher provide for annual salaries of \$200,000 each and the agreement with Mr. Oertle provides for an annual salary of \$150,000. Pursuant to the terms of the agreements, each of these stockholders is eligible to participate in the Company's long term incentive compensation programs and is entitled to an annual bonus if the Company meets or exceeds criteria adopted by the 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.

### *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.

### *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.

### **13. 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 July 3, 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.

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

### **ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

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

### ***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.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

Not applicable.

### **Item 4. Controls and Procedures.**

#### **Evaluation of Disclosure Controls and Procedures**

Our principal executive officer and principal financial officer have evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a – 15(e) and 15d – 15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as of the end of the period covered by this quarterly report. They have concluded that, based on such evaluation, our disclosure controls and procedures were not effective due to the material weaknesses in our internal control over financial reporting as of September 30, 2012, as described in our Form 10-K for the year ended December 31, 2011 filed with the SEC on April 16, 2012.

## Changes in Internal Controls Over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II – OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

*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, BioZone Pharma and a former officer and director 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.

*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.

*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.

### **ITEM 1A. RISK FACTORS**

None

## **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

On April 25, 2012, certain holders of 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 June 28, 2012, the holder of the September 2011 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.

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.

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.

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 above referenced issuances did not involve any underwriters, underwriting discounts or commissions, or any public offering. The issuance of these securities was deemed to be exempt from the registration requirements of the Securities Act of 1933 as amended, by virtue of Section 4(2) thereof, as a transaction by an issuer not involving a public offering.

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable

## **ITEM 5. OTHER**

None

## **ITEM 6. EXHIBITS**

31.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)

32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith)

101\* The following materials from Biozone Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 are formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Statements of Cash Flow, (iii) the Consolidated Balance Sheets, and (iv) the Notes to the Consolidated Financial statements tagged as blocks of text.

\* In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Amendment to our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2012 shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.



**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**BioZone Pharmaceuticals, Inc.**

Dated: November 14, 2012

By: /s/ Elliot Maza

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

**CERTIFICATION**

I, Elliot Maza, certify that:

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

Dated: November 14, 2012

/s/ Elliot Maza

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

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Biozone Pharmaceuticals, Inc., a Nevada corporation (the "Company"), on Form 10-Q for the period ended September 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Elliot Maza, Chief Executive Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Dated: November 14, 2012

/s/ Elliot Maza

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

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