True Drinks Holdings, Inc.
Form 10-K
April 05, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

[X] ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2012

or

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

Commission file No. 001-32420

TRUE DRINKS HOLDINGS, INC.
(formerly known as Bazi International, Inc.)
(Exact name of registrant as specified in its charter)

Nevada	84-1575085
(State of incorporation)	(I.R.S. Employer Identification Number)

18552 MacArthur Blvd, Suite 325
Irvine, CA 92612
(Address of principal executive offices)

(949) 203-3500
(Issuer's telephone number)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock ($0.001 par value)	Over the Counter

Securities registered under Section 12(g) of the Exchange Act: None

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

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

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 [X] No [ ]

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

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

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

Large accelerated filer [ ]	Accelerated filer [ ]	Non-accelerated filer [ ]	Smaller reporting company [X]

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

The aggregate market value of common stock held by non-affiliates as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2012, was approximately $6,873,500 based on a closing market price of $0.09 per share (pre-split).

There were 26,788,352 shares of the registrant's common stock outstanding as of March 29, 2013.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains “forward-looking” statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and is subject to the safe harbor created by those sections. We intend to identify forward-looking statements in this report by using words such as “believes,” “intends,” “expects,” “may,” “will,” “should,” “plan,” “projected,” “contemplates,” “anticipates,” “estimates,” “predicts,” “potential,” “continue terminology. These statements are based on our beliefs as well as assumptions we made using information currently available to us. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise. Because these statements reflect our current views concerning future events, these statements involve risks, uncertainties, and assumptions. Actual future results may differ significantly from the results discussed in the forward-looking statements. These risks include changes in demand for our products, changes in the level of operating expenses, our ability to expand our network of customers, changes in general economic conditions that impact consumer behavior and spending, product supply, the availability, amount, and cost of capital to us and our use of such capital, and other risks discussed in this report. Additional risks that may affect our performance are discussed below under “Risk Factors Associated with Our Business.”

PART I

ITEM 1. DESCRIPTION OF BUSINESS

As used in this Annual Report, “we”, “us”, “our”, “True Drinks”, “Company” or “our Company” refers to True Drinks, Inc. ar of its subsidiaries, unless the context requires otherwise. We are a holding company and conduct no operating business, except through our subsidiaries. During January 2013, we changed our name from True Drinks, Inc. to True Drinks Holdings, Inc.

Overview

True Drinks, Inc. (the "Company"), is a beverage company that specializes in all-natural, vitamin-enhanced drinks. Our primary business is the development, marketing, sale and distribution of our flagship product, AquaBallTM Naturally Flavored Water, a vitamin-enhanced, naturally flavored water drink packaged in our patented stacking spherical bottles. We distribute the AquaBallTM nationally through select retail channels, such as grocery stores, mass merchandisers, drug stores and online. We also market and distribute Bazi® All Natural Energy, a liquid nutritional supplement drink, which is currently distributed online and through our existing database of customers.

The Company was originally incorporated in the state of Delaware in January 2012.

Our principal place of business is 18552 MacArthur Boulevard, Suite 325, Irvine, California, 92612. Our telephone number is (949) 203-2500. Our corporate website address is http://www.truedrinks.com. Our common stock, par value $0.001 (“Common Stock”) is currently listed for quotation on the Over-the-Counter Bulletin Board (“OTCBB”) under the symbol TRUU.

Recent Developments

Reverse Merger with Bazi International, Inc. ("Bazi Intl.")

On June 7, 2012, the Company, Bazi Acquisition Sub Inc. ("Merger Sub"), a Delaware corporation and a wholly-owned subsidiary of the Bazi Intl., and True Drinks entered into an agreement and plan of merger (the “Merger Agreement”), wherein Merger Sub merged with and into True Drinks and True Drinks continued as the surviving

corporation (the "Merger"). As a result of the Merger, True Drinks became a wholly-owned subsidiary of the Company. The Merger closed on October 15, 2012 (the “Closing Date”). The Merger was accounted for as a public company “reverse merger,” and, as such, the consolidated financial statements reported herein reflect the operations of True Drinks, Inc. as the accounting acquiror within the new capital structure of the Company effective on the closing date.

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On the Closing Date, the executives and Board of Directors of True Drinks, Inc. were appointed to the same positions within True Drinks Holdings, Inc. Lance Leonard was appointed as our Chief Executive Officer, Daniel Kerker as our Chief Financial Officer, and Kevin Sherman, former President of the Company, as our Vice President of Marketing. We also appointed Timothy Lane, Carl Wistreich, Lou Imbrogno and Lance Leonard to fill the vacancies on our Board of Directors created as a result of the resignation of the former directors of Bazi International, Inc.

Creation of the Series A Preferred

Upon closing the Merger, the Company filed a Certificate of Designation, Preferences, Rights and Limitations of Series A Convertible Preferred Stock ("Series A Preferred") (the "Certificate of Designation"), creating 1,544,565 shares of Series A Preferred. On the Closing Date, former True Drinks shareholders exchanged all outstanding capital stock of True Drinks for a total of 1,544,565 Series A Preferred, which shares represent on an as-converted basis at a conversion rate of $0.00610403 per share approximately 95.5% of the total Common Stock outstanding at December 31, 2012. As explained below, the Series A Preferred automatically converted into a total of 2,530,399,062 shares of Common Stock on January 18, 2013.

Financings

In November and December 2012, the Company issued an aggregate principal amount of $725,000 in unsecured convertible promissory notes (the "Notes") to certain purchasers (the "Purchasers"). The Notes had a term of 120 days and bore interest at a rate of 9% per annum. At maturity, the holders of the Notes have the right to convert all principal and accrued interest due thereunder into Common Stock at a conversion price equal to $0.01 per share. In addition, each Purchaser received 500,000 shares of Common Stock per $25,000 of principal amount held.

In December 2012, the Company issued $47,000 in unsecured promissory notes to certain purchasers. The notes had a term of 30 days and paid a lender's fee of 10% of principal. The notes were repaid in January, 2013.

On January 14, 2013, we completed a private placement, wherein we issued an aggregate principal amount of $575,000 in unsecured convertible promissory notes (the "January Notes") to certain purchasers. The January Notes had a term of 120 days and bore interest at a rate of 9% per annum. At maturity, the holders of the January Notes have the right to convert all principal and accrued interest due thereunder into Common Stock at a conversion price equal to $0.01 per share. In addition, each purchaser received 500,000 shares of Common Stock per $25,000 of principal amount held.

Amendment to our Articles of Incorporation and Reverse Stock Split

On January 18, 2013, we filed an amendment to our Articles of Incorporation (the "Amendment") to (i) to change our name to True Drinks Holdings, Inc., and (ii) increase the total number of authorized shares of Common Stock from 200,000,000 to 4,000,000,000 shares. Upon the filing of the Amendment, the shares of Series A Preferred issued to former True Drinks shareholders automatically converted into approximately 2,530,399,062 shares of Common Stock.

In addition, on January 18, 2013, following the Amendment, we affected a reverse split of our authorized, issued and outstanding shares of Common Stock on a 100 for 1 basis. Accordingly, our authorized Common Stock decreased from 4,000,000,000 to 40,000,000 shares and our issued and outstanding shares of Common Stock decreased from 2,649,632,531 to 26,496,325 shares as of January 18, 2013.

The name change and reverse split became effective with the Over−the−Counter Bulletin Board at the opening of trading on January 22, 2013.

Option Agreement

On January 14, 2013, we entered into an Option Agreement (the "Option Agreement") with Ashworth Holdings, LLC, a Utah limited liability company ("Ashworth"), pursuant to which Ashworth shall have the option to purchase up to 86,008,650 shares of Common Stock for a price of $0.00549 per share and shall expire on April 30, 2013 or upon Ashworth's exercise of the full allotment of shares thereunder. Upon the 1 for 100 reverse split of the Company's Common Stock on January 18, 2013, the Option Agreement has been adjusted to cover the purchase of 860,087 shares of Common Stock for a price of $0.549 per share.

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Our History

Bazi Intl. Prior to Merger with True Drinks, Inc.

Bazi Intl. was formed in 2001, under the name "Instanet, Inc." In August 2010, we changed our name to Bazi International, Inc. Until January 18, 2010, our principal channel of distribution was through a multilevel distributor network, which we terminated in January 2010 in favor of a retail and direct-to-consumer, online sales model. Bazi Intl. continued to distribute Bazi® online and through our existing database of customers, but as a result of the termination of our multilevel distributor model, most of our top distributors ended their relationship with the Company during the first quarter of 2010, causing sales of Bazi® to decrease throughout 2011 and into 2012. As a result, Bazi Intl. began suffering from a lack of sufficient capital necessary to adequately market Bazi® and support the Company's existing retail and distribution partners.

True Drinks, Inc. Prior to Merger with the Bazi Intl.

True Drinks, Inc. (formerly GT Beverage Company, Inc.) was formed on January 19, 2012 to develop, market and sell AquaBallTM Naturally Flavored Water. In February and March of 2012, True Drinks, Inc. acquired GT Beverage Company, LLC, the predecessor entity to True Drinks, Inc. GT Beverage Company, LLC was formed in May 2008 to create and commercialize its Sportastic® brand sports drink, sold in round plastic bottles with registered trade dresses such as baseball and soccer designs. However, in January 2012, GT Beverage Company, LLC ceased its sports drink operations. True Drinks began packaging and selling AquaBallTM Naturally Flavored Water in its patented interlocking round plastic bottles, with depictions of characters from major entertainment companies, as permitted by licensing agreements with these companies.

Market Overview

Our products are characterized as functional beverages, or drink products with specific health benefits in its formulation of ingredients. Our flagship product, AquaBallTM Naturally Flavored Water is a healthy hydration alternative to current beverages positioned towards children, and competes in the kids' food market segment. Functional beverages are growing at an aggressive rate, largely due to consumer demand for healthier alternatives to typical carbonated soft drinks. The shift away from carbonated soft drinks to healthier, functional drinks is reflected in the fact that sales of carbonated soft drinks have been flat since 2004, yet functional beverage sales have grown almost $20.0 billion over the same period to $30.6 billion in annual sales. Market research firm Zenith International estimates that global per capita consumption of functional beverages increased 25% from 2010 to 2013.

The kids foods market segment is projected to grow 40% from $10 billion in 2010 to $14 billion by 2015 according to Packaged Facts, a leading publisher of market research in the food, beverage and consumer packaged good sectors. Beverages are the second highest performing product within the kids foods market segment. In 2010, 40% of the kids food market contained some "better-for-you" element. Packaged Foods forecasts that the next several years will bring tremendous growth in the sales and development of food and beverage products marketed and designed for children. As a result, we are currently positioning AquaBallTM as a healthy, safe, naturally flavored water drink for kids.

Our Products

We market and distribute products that move away from high sugar, high calorie and nutritionally deficient beverages to healthful, natural alternatives. Our mission is to bring integrity back to the beverage industry and that honesty applies to every drop in every bottle. Our goal is to create and deliver beverages for families that encourage improved

health, while being clear about what our products contain (and what they don’t).

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AquaBallTM Naturally Flavored Water

Our flagship product, AquaBallTM Naturally Flavored Water, is a naturally flavored water beverage, enhanced with vitamins B3, B5, B6, B12 and C. AquaBallTM does not contain high fructose corn syrup, artificial flavors, or artificial colors. Unlike high sugar and high calorie beverages marketed toward children, AquaBallTM is sweetened with stevia, an all-natural sweetener, allowing the AquaBallTM to provide a zero-sugar, zero-calorie alternative to juice and soda for kids. The main component of the marketing vision behind the AquaBallTM brand is our licensing agreements with Disney Consumer Products, Inc. ("Disney") and Marvel Entertainment ("Marvel"), allowing each AquaBallTM to prominently feature various Disney and Marvel characters. Both Disney and Marvel characters have an established reputation of high retail sales of licensed products, giving each AquaBallTM the presence associated with these brands.

Each AquaBallTM is packaged in our patented 12 ounce stackable, spherical PET bottle, and wrapped with colorful, eye-catching labels featuring popular Disney characters and various Marvel Superheros. AquaBallTM currently comes in grape, orange and fruit punch flavors, and is sold in mass-market retailers throughout the United States. AquaBallTM is also available for purchase online at http://www.theaquaball.com. During the year ended December 31, 2012, AquaBallTM sales accounted for approximately 99% of the Company's total revenues.

Bazi®

Bazi® All Natural Energy, is a liquid nutritional drink packed with eight different super fruits, including the Chinese jujube and seven other superfruits, plus 12 vitamins. The proprietary formula contains the following fruits: jujube fruit, blueberry, pomegranate, goji berry, chokeberry, raspberry, acai and sea buckthorn. Additionally, Bazi® contains 12 vitamins including vitamins A, C, E and B-complex. In August, 2011, BioEnergy Ribose was added to Bazi® enhancing the products energy delivery system. Following the Merger, Bazi® sales accounted for approximately 1% of our total revenue from October 15, 2012 through the end of the fiscal year.

Manufacturing and Distribution

Manufacturing

We use a limited number of third parties to supply and manufacture our products. We have co-packing agreements with 7-Up Bottling in Modesto, California and Coats International, Inc. in Dallas, Texas to package up to 2.5 million AquaBallTM cases per year. Bazi® is manufactured by Arizona Packaging and Production under the terms of a five year exclusive manufacturing agreement, which stipulates certain prices, quantities and delivery timelines.

Retail Distribution

We utilize a direct-to-retailer distribution strategy to key national accounts for sales of AquaBallTM Naturally Flavored Water, including distribution to Toys R Us, Inc. and stores under the Safeway, Inc. brand nationwide. We also distribute AquaBallTM through regional distributors throughout the United States. We are actively seeking additional retail and convenience accounts, and we plan to explore alternative markets for AquaBallTM in the upcoming year such as schools, sports venues, fast food restaurants, dollar store and club store channels. Additionally, our licensing agreement with Disney Consumer Products, Inc. and Marvel Entertainment allows us to work with Disney and Marvel's dedicated sales teams who, in turn, work with top retailers to assist us with securing shelf-space for AquaBallTM and accomplishing our long-term sales objectives.

Online Sales.

The Company's ecommerce platform allows current and future consumers to purchase AquaBallTM Naturally Flavored Water and Bazi® Energy Shot by visiting our newly redesigned webpages, http://www.theaquaball.com and http://www.drinkbazi.com. We drive traffic to relevant landing pages and micro sites through digital marketing campaigns and promotions, and a variety of social media marketing efforts.

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Sales and Marketing

The Company's sales and marketing efforts are directed from our corporate offices in Irvine, California, utilizing our own staff, as well as outside resources retained to build market awareness and shelf placement of our products. The Company manages key national accounts through our in-house national sales team. Our sales teams work to secure national distribution with these customers through multiple avenues including joint sales meetings with Disney and Marvel sales personnel dedicated to these national accounts. The Company has hired outside personnel to manage our national broker networks. The networks focus on areas such as regional grocery chains, the convenience store channel, and the food service segment.

The Company is not dependent upon any major customers.

Source and Availability of Raw Materials

We utilize a variety of suppliers to purchase raw materials for the AquaBallTM Naturally Flavored Water during the year ended December 31, 2012.

During 2012, we relied significantly on one supplier for 100% of our purchases of raw materials for Bazi®. Bazi, inc. entered into an exclusive manufacturing agreement with this supplier in 2007 to produce the Bazi® product.

We own the formulas for both AquaBallTM Naturally Flavored Water and Bazi® Energy Shot, and we believe that our purchasing requirements can be readily met from alternative sources, if necessary.

Competition

The industries in which we operate are highly competitive. Not only do we compete with other manufacturers of functional beverages but we also compete with manufacturers of more traditional beverages, such as juice and soda marketed to children.

Our competition in the beverage industry includes products owned by multinational corporations with significant financial resources, including Vitamin Water and Tum-E Yummies, owned by Coca-Cola, and Sobe and Propel, owned by Pepsi Co. Bazi® competitors include Steaz®, Guayaki Yerba Mate, POM Wonderful®, as well as sports and energy drinks including Gatorade®, Red Bull®, 5-Hour Energy®, RockStar®, Monster®, Powerade®, Accelerade® and All Sport®. Indirect competition for the AquaBallTM and Bazi® includes soft drinks and juice products, such as Sunny Delight®, CapriSun® and other fruit drinks. These competitors can use their resources and scale to rapidly respond to competitive pressures and changes in consumer preferences by introducing new products, reducing prices or increasing promotional activities. Many of our competitors have longer operating histories and have substantially greater financial and other resources than we do. They therefore have the advantage of established reputations, brand names, track records, back office and managerial support systems and other advantages that we cannot duplicate in the near future. Moreover, many competitors, by virtue of their longevity and capital resources, have established lines of distribution to which we do not have access, and are not likely to duplicate in the near term, if ever.

Intellectual Property

We rely on the AquaBallTM patent, AquaBallTM and Bazi® trademarks and licensing agreements to market our products and make them standout among out competitors.

Patents and Trademarks

We were granted the patent for AquaBallTM's stackable, spherical drink container in 2009, via our predecessor entity GT Beverage Company, LLC, who we purchased on March 31, 2012. We maintain trademark protection for AquaBallTM and have federal trademark registration for Bazi®. This trademark registration is protected for a period of ten years and then is renewable thereafter if still in use.

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Licensing Agreements

We entered into a three-year licensing agreement with Disney Consumer Products, Inc. (“Disney”) and an 18-month licensing agreement with Marvel Characters, B.V. ("Marvel") (the “Licensing Agreements”) in 2012. Each Licensing Agreement allows us to feature popular Disney and Marvel characters on AquaBallTM Naturally Flavored Water, allowing AquaBallTM to stand out among other beverages marketed towards children. Under the terms and conditions of the Licensing Agreements, we work with the Disney and Marvel teams to create colorful, eye-catching labels that surround the entire spherical shape of each AquaBallTM. Once the label designs are approved, we work with Disney and Marvel to set retail calendars, rotating the placement of different AquaBallTM designs over the course of the year. The terms of the Disney Licensing Agreement stipulates a royalty rate of 4% on the sales of AquaBall Naturally Flavored Water adorned with Disney characters, paid quarterly, with a total royalty guarantee of $231,600 over the term of the agreement which has a term ending date of March 31, 2015. In addition, the Company is required to spend 1% of sales on advertising and promotional opportunities. The Company is required to make common marketing fund contributions totaling $96,188 over the life of the agreement.

The terms of the Marvel Licensing Agreement stipulates a royalty rate of 5% on the sales of AquaBall Naturally Flavored Water adorned with Marvel characters, paid quarterly, with a total royalty guarantee of $150,000 over the term of the agreement which has a term ending date of December 31, 2013.

Government Regulations

General

Our operations are affected by extensive laws, governmental regulations, administrative determinations, court decisions and enforcement policies. These requirements exist at the federal, state and local levels in the United States, including laws and regulations pertaining to:

- the formulation, manufacturing, packaging, labeling, holding, storage, distribution, advertising and sale of our products; and

- product claims and advertising, including direct claims and advertising by us, as well as claims and advertising by independent distributors, for which we may be held responsible.

The formulation, manufacturing, packaging, labeling, holding, storage, distribution, advertising, and sale of our products is subject to regulation by one or more federal agencies, including the Food and Drug Administration (“FDA”), the Federal Trade Commission (“FTC”), the Consumer Product Safety Commission (“CPSC”), the Occupational Safety and Health Administration (“OSHA”), the Department of Agriculture (“USDA”) and the Environmental Protection Agency (“EPA”). These activities are also regulated by various agencies of the states and localities in which our products are sold. Pursuant to the Federal Food, Drug, and Cosmetic Act (“FDCA”), the FDA regulates the processing, formulation, safety, manufacture, packaging, labeling, holding, sale, and distribution of foods and nutritional supplements (including vitamins, minerals, amino acids, herbs, and botanicals). The FTC has jurisdiction to regulate the advertising of these products. The CPSC is charged with protecting the public from risks of serious injury or death associated with the use of consumer products. Nutritional supplements are among the over 15,000 types of consumer products under CPSC’s jurisdiction. When consumers complain to the CPSC about alleged harm stemming from ingestion of vitamins and other nutritional supplement, CPSC may contact the entity concerned, inform it of the nature of the complaint, and invite a response. CPSC has conducted several recalls of iron-containing dietary supplements that do not comply with the child-resistant packaging requirement. The OSHA is charged with protecting workplace

safety. Nutritional supplement companies must maintain a safe workplace and may from time to time be subject to queries from OSHA if manufacturing methods or procedures raise a question of worker safety. The USDA has jurisdiction over animal food and animal feed, including regulatory control over the harvesting of animal-based source materials, including animal-derived proteins, and animal-derived gelatin capsules, used in the making of dietary supplements. The EPA regulates dietary supplement compliance with standards established under the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, and the Pollution Prevention Act as they affect the use, maintenance, and disposal of substances used in and facilities used for the manufacture of nutritional supplements.

The FDCA has been amended several times with respect to nutritional supplements, in particular by the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), which established a new framework governing the composition, safety, labeling and marketing of nutritional supplements. Nutritional supplements are defined as vitamins, minerals, herbs, other botanicals, amino acids and other dietary substances for human use to supplement the diet, as well as concentrates, metabolites, constituents, extracts or combinations of such dietary ingredients. Generally, under DSHEA, dietary ingredients that were on the market prior to October 15, 1994, may be used in nutritional supplements without notifying the FDA. New dietary ingredients, consisting of dietary ingredients that were not marketed in the United States before October 15, 1994, are subject to a FDA pre-market new dietary ingredient notification requirement unless the ingredient has been present in the food supply as an article used for food without being chemically altered. A new dietary ingredient notification must provide the FDA with evidence of a history of use or other evidence of safety establishing that use of the dietary ingredient will reasonably be expected to be safe. A new dietary ingredient notification must be submitted to the FDA at least 75 days before the initial marketing of the new dietary ingredient. There is no certainty that the FDA will accept any particular evidence of safety for any new dietary ingredient. The FDA's refusal to accept such evidence could prevent the marketing of such dietary ingredients.

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The FDA issued a consumer warning in 1996, followed by proposed regulations in 1997, covering nutritional supplements that contain ephedra or its active substance, ephedrine alkaloids. We have never produced or sold products containing ephedra. In February 2004, the FDA issued a final regulation declaring nutritional supplements containing ephedra under the FDCA because they present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use. The rule took effect on April 12, 2004, and bans the sale of nutritional supplement products containing ephedra. Similarly, the FDA issued a consumer advisory in 2002 with respect to nutritional supplements that contain the ingredient Kava, and the FDA is currently investigating adverse effects associated with ingestion of this ingredient. We have never produced or sold any products containing Kava.

DSHEA permits statements of nutritional support to be included in labeling for nutritional supplements without FDA premarket approval. These statements must be submitted to the FDA within 30 days of marketing and must bear a label disclosure that "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." These statements may describe a benefit related to a nutrient deficiency disease, the role of a nutrient or nutritional ingredient intended to affect the structure or function in humans, the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, the general well-being from consumption of a nutrient or dietary ingredient, but may not expressly or implicitly represent that a nutritional supplement will diagnose, cure, mitigate, treat or prevent a disease. An entity that uses a statement of nutritional support in labeling must possess scientific evidence substantiating that the statement is truthful and not misleading. If the FDA determines that a particular statement of nutritional support is an unacceptable drug claim or an unauthorized version of a disease claim for a food product, or if the FDA determines that a particular claim is not adequately supported by existing scientific data or is false or misleading, we would be prevented from using the claim.

In addition, DSHEA provides that so-called "third-party literature," e.g., a reprint of a peer-reviewed scientific publication linking a particular nutritional ingredient with health benefits, may be used in connection with the sale of a nutritional supplement to consumers without the literature being subject to regulation as labeling. Such literature must not be false or misleading; the literature may not promote a particular manufacturer or brand of nutritional supplement; the literature must present a balanced view of the available scientific information on the nutritional supplement; if displayed in an establishment, the literature must be physically separate from the nutritional supplement; and the literature may not have appended to it any information by sticker or any other method. If the literature fails to satisfy each of these requirements, we may be prevented from disseminating it with our products, and any dissemination could subject our products to regulatory action as an illegal drug. Moreover, any written or verbal representation by us that would associate a nutrient in a product that we sell with an effect on a disease will be deemed evidence of an intent to sell the product as an unapproved new drug, a violation of the FDCA.

On August 25, 2007 the FDA adopted the final regulations for large manufactures of a standard originally proposed in March 2003 of the current Good Manufacturing Practices guidelines ("cGMPs") for the manufacturing, packing, holding and distributing dietary ingredients and nutritional supplements. The new regulations will require nutritional supplements to be prepared, packaged, and held in compliance with strict rules, and will require quality control provisions that may mandate redundant testing of product ingredients at each separate stage of manufacture and are intended to ensure that products are accurately labeled and don't contain adulterants and contaminants. While the rule allowed for medium and small manufacturers to have until 2009 and 2010, respectively, to comply with the cGMPs, most of our contract manufacturers did not qualify as small or medium. As a result, many of our contract manufacturers began following the proposed cGMPs or even pharmaceutical cGMPs well before the final rule was published. We expect to see an increase in our manufacturing costs as a result of the necessary increase in testing of raw ingredients and finished products and compliance with higher quality standards, although we are not certain of the amount of these costs.

The FDA has broad authority to enforce the provisions of the FDCA applicable to nutritional supplements, including powers to issue a public warning letter to an entity, to publicize information about illegal products, to request a recall of illegal products from the market, and to request the Department of Justice to initiate a seizure action, an injunction action, or a criminal prosecution in the United States courts. The regulation of nutritional supplements may increase or become more restrictive in the future.

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In 2004, legislation was introduced in both houses of Congress that imposed substantial new regulatory requirements for dietary supplements. These bills did not pass and are no longer pending, but we believe the 2004 proposed legislation evidences a continuing effort to further regulate dietary supplements.

On April 12, 2004, the FDA adopted a new test for determining when a nutritional supplement is adulterated. Under this test, the FDA may declare a nutritional supplement adulterated (i.e., to present an unreasonable risk of illness or injury) if it finds any benefit provided by the supplement outweighed by a risk of illness of injury. The new risk/benefit test is ill-defined and can be interpreted to permit FDA to hold a wide range of nutritional supplements adulterated. It is possible that FDA might hold more nutritional supplements adulterated in the future, reducing the nutritional ingredients available for use in our products.

The FTC exercises jurisdiction over the advertising of nutritional supplements. In recent years, the FTC has instituted numerous enforcement actions against nutritional supplement companies for deceptive advertising based on those companies' alleged failure to possess competent and reliable scientific evidence in support of claims made in advertising.

The FTC may monitor our advertising and could request all evidence in support of our advertising claims, which evidence is required to be kept by us in advance of advertising. Discerning what constitutes "competent and reliable scientific evidence" involves, to a degree, a subjective assessment of the relative level, degree, quality, and quantity of scientific evidence and its acceptance in the scientific community as proof of the advertising statement. It is therefore possible that we may think evidence we have as sufficient but the FTC may deem the evidence inadequate. We believe we are in material compliance with applicable federal, state and local rules.

On December 9, 2006, President Bush signed the Dietary Supplement & Nonprescription Drug Consumer Protection Act into law. The legislation requires manufacturers of dietary supplement and over-the-counter products to notify the FDA when they receive reports of serious adverse events. We already have an internal adverse event reporting system that has been in place for several years. In December 2008 the FDA submitted Guidance for implementing the regulations for comment, this guidance, when finalized, will represent the current thinking of the Food and Drug Administration on this topic, which we would intend to fully comply with.

We believe that current and reasonably foreseeable governmental regulation will have minimal impact on our business.

Research and Development

No expenses were recorded on research and development for the year ended December 31, 2012. During 2012, we developed our AquaBallTM proprietary formula along with Wild Flavors, Inc., an independent third party contracted by the Company. We launched AquaBallTM in June 2012. The AquaBallTM did not require FDA or other regulatory approval. Following the initial launch of the AquaBallTM , we