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

FORM 10-K

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

For the fiscal year ended December 31, 2015

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

For the transition period from _____ to _____

Commission File Number 333-181719

CARDAX, INC.

(Exact name of registrant as specified in its charter)

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

45-4484428
*(I.R.S. Employer
Identification No.)*

2800 Woodlawn Drive, Suite 129
Honolulu, Hawaii
(Address of principal executive offices)

96822
(Zip code)

(808) 457-1400

(Registrant's telephone number, including area code)

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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
Non-accelerated filer (Do not check if a smaller reporting company)

Accelerated filer
Smaller reporting company

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

As of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, there were 67,747,771 shares of common stock, par value \$0.001 per share, outstanding, and 34,747,771 of such shares were held by non-affiliates. As of such date, the

aggregate market value of voting and non-voting common equity held by non-affiliates was \$6,949,554.

As of March 28, 2016 there were 69,087,955 shares of common stock, par value \$0.001 per share ("common stock"), of the registrant outstanding.

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PART I

ITEM 1. BUSINESS.

Explanatory Note

Unless otherwise noted, references in this Annual Report on Form 10-K to “Cardax,” the “Company,” “we,” “our,” or “us” means Cardax, Inc., the registrant, and, unless the context otherwise requires, together with its wholly-owned subsidiary, Cardax Pharma, Inc., a Delaware corporation (“Pharma”), and Pharma’s predecessor, Cardax Pharmaceuticals, Inc., a Delaware corporation (“Holdings”), which merged with and into Cardax, Inc. on December 30, 2015.

Special Note Regarding Forward-Looking Statements

There are statements in this annual report that are not historical facts. These “forward-looking statements” can be identified by use of terminology such as “anticipate,” “believe,” “estimate,” “expect,” “hope,” “intend,” “may,” “plan,” “positioned,” “project,” “propose,” “should,” “strategy,” “will,” or any similar expressions. You should be aware that these forward-looking statements are subject to risks and uncertainties that are beyond our control. For a discussion of these risks, you should read this entire annual report carefully, especially the risks discussed under the section entitled “Risk Factors.” Although we believe that our assumptions underlying such forward-looking statements are reasonable, we do not guarantee our future performance, and our actual results may differ materially from those contemplated by these forward-looking statements. Our assumptions used for the purposes of the forward-looking statements specified in the following information represent estimates of future events and are subject to uncertainty as to possible changes in economic, legislative, industry, and other circumstances, including the development, acceptance and sales of our products and our ability to raise additional funding sufficient to implement our strategy. As a result, the identification and interpretation of data and other information and their use in developing and selecting assumptions from and among reasonable alternatives require the exercise of judgment. In light of these numerous risks and uncertainties, we cannot provide any assurance that the results and events contemplated by our forward-looking statements contained in this annual report will in fact transpire. **These forward-looking statements are not guarantees of future performance. You are cautioned to not place undue reliance on these forward-looking statements, which speak only as of their dates.** We do not undertake any obligation to update or revise any forward-looking statements, except as required by law.

Cautionary Note Regarding Industry Data

Unless otherwise indicated, information contained in this annual report concerning our company, our business, the services we provide and intend to provide, our industry and our general expectations concerning our industry are based on management estimates. Such estimates are derived from publicly available information released by third party sources, as well as data from our internal research, and reflect assumptions made by us based on such data and our knowledge of the industry, which we believe to be reasonable.

Overview

We are a life sciences company that develops consumer health and pharmaceutical technologies and we are a smaller reporting company as defined by applicable federal securities regulations.

The following events summarize the material transactions of our history and acquisition of our life science business:

May 5, 2006: Holdings acquired the intellectual property and other assets regarding certain astaxanthin technologies from Hawaii Biotech, Inc., a Delaware corporation (“HBI”), in exchange for shares of common stock of Holdings, shares of preferred stock of Holdings, options to purchase shares of common stock of Holdings and the assumption by Holdings of certain liabilities of HBI. At this date, Holdings became a separate company with the initial life-science astaxanthin technologies.

May 5, 2006 to May 31, 2013: Holdings continued the research and development of astaxanthin technologies and related compounds and raised capital primarily through the issuance of debt securities.

January 30, 2012: We were incorporated in Delaware under the name “Koffee Korner Inc.” At this time, we acquired all the capital stock of Koffee Korner’s Inc, a Texas corporation (“Koffee Sub”), which operated as a single location retailer of specialty coffee in Houston, Texas.

- May 16, 2013: Pharma was formed as a wholly owned subsidiary of Holdings.
- May 31, 2013: Holdings contributed its assets to Pharma in exchange for all of the capital stock of Pharma and the assumption by Pharma of all of the liabilities of Holdings.
- May 31, 2013 to February 7, 2014: Pharma continued the business of Holdings including the research and development of consumer health and pharmaceutical technologies and the commercialization of our technologies for products, and raised capital through the offering of senior secured convertible promissory notes.
- November 25, 2013: We formed Cardax Acquisition, Inc., a Delaware corporation (“Cardax Sub”), as our wholly owned subsidiary as part of a corporate structure to enable the merger of Cardax Sub with and into Pharma, which would result in our acquisition of the consumer health and pharmaceutical business of Pharma
- January 10, 2014: We made our first investment in Pharma by purchasing 40% of the Pharma common stock (determined after our purchase of such shares) in exchange for shares of our common stock. At this point, our assets were: Koffee Sub, Cardax Sub, and our investment in Pharma.
- February 7, 2014: We consummated the merger (the “Merger”) of Cardax Sub with and into Pharma, and Pharma became our wholly owned subsidiary. We divested Koffee Sub and exclusively continued the consumer health and pharmaceutical business of Pharma. On this date, we amended and restated our certificate of incorporation and bylaws and changed our name to “Cardax, Inc.”
- December 30, 2015: We consummated the merger (the “Holdings Merger”) of Holdings with and into us. Upon the closing of the Holdings Merger, the stockholders of Holdings received an aggregate number of shares and warrants to purchase shares of our common stock equal to the aggregate number of shares of our common stock that were held by Holdings on the date of the closing of the Holdings Merger. Our restricted shares of common stock held by Holdings were cancelled upon the closing of the Holdings Merger. Accordingly, there was not any change to our fully diluted capitalization due to the Holdings Merger.

Our executive offices are located at 2800 Woodlawn Drive, Suite 129, Honolulu, Hawaii 96822; our telephone number is (808) 457-1400. Our website is located at <http://www.cardaxpharma.com>. The information on our website is not part of this annual report.

Our Business

We are a pre-revenue life sciences company devoting substantially all of our efforts to developing consumer health and pharmaceutical technologies for products that we believe will provide many of the anti-inflammatory benefits of steroids or non-steroidal anti-inflammatory drugs (“NSAIDs”) by targeting many of the same inflammatory pathways and mediators, but with exceptional safety profiles. We will use our proprietary technologies to develop and commercialize products and related derivatives that have the same or substantially similar properties as occurring in nature or “nature-identical,” by total synthesis to provide scalable, pure, and economical therapies for diseases where inflammation and oxidative stress are strongly implicated, including, but not limited to, osteoarthritis, rheumatoid arthritis, dyslipidemia, metabolic disease, diabetes, cardiovascular disease, hepatitis, cognitive decline, macular degeneration, and prostate disease. The safety and efficacy of our product candidates have not been directly evaluated in clinical trials or confirmed by the FDA.

Many anti-inflammatory drugs have significant safety risks and side effects that limit their utility, especially in treating a chronic disease. We believe that our ability to develop and commercialize proprietary, nature-identical products and related derivatives should provide us with a competitive advantage through a novel treatment approach that combines robust efficacy with safety, oral bioavailability, and tissue selectivity. To date, we have not produced and commercialized any products or generated any revenues from our life sciences business.

Strategic Alliances

We intend to expand our capabilities for the development, manufacturing, formulation, marketing and distribution or other exploitation of products based on our proprietary technologies by entering into one or more strategic alliances with companies that have established capabilities.

In November 2006, we entered into a Joint Development and Supply Agreement (the “BASF Agreement”) with BASF, relating to the research, development, manufacture, commercialization and related matters, and the related intellectual property rights with respect to consumer health or “nutraceutical” and pharmaceutical products containing or utilizing synthetically manufactured astaxanthin in the geometric (*trans*) and optical (*S,S'*) isomeric form most prevalent in nature (“ASTX-1”), which is the same geometric and optical isomeric form of astaxanthin found in GRAS-designated microalgal astaxanthin products. Under the BASF Agreement, we have granted BASF an exclusive worldwide license to our rights related to the development and commercialization and related obligations of consumer health products containing or utilizing ASTX-1 (“BASF Astaxanthin Products”). This license will provide us with potential benefits including specified royalties for future net sales of BASF Astaxanthin Products, from and after the development and manufacture and applicable regulatory approval of any such BASF Astaxanthin Products. The BASF Agreement does not prohibit Cardax from purchasing BASF Astaxanthin Products for consumer health applications and provides that BASF will manufacture and supply Cardax on a mutually exclusive basis with preclinical, clinical, and commercial scale amounts of ASTX-1 for pharmaceutical applications. The BASF Agreement is subject to certain termination rights of the parties. If any termination is a result of the non-renewal of the then current term of the agreement or because BASF no longer manufactures astaxanthin, then the terminating party shall, upon the request of the non-terminating party, grant the non-terminating party a reasonable royalty-bearing, irrevocable, worldwide non-exclusive license of certain intellectual property rights of the terminating party that will enable the non-terminating party to continue the manufacture and distribution of BASF Astaxanthin Products. Either party may also terminate the BASF Agreement if there is a change of a controlling interest in the other party; however, the provision shall not apply if a party that is not a manufacturer of synthetic carotenoids acquires the Company. The BASF Agreement provides for an initial term of three years that is automatically extended for 18 month periods unless notice of termination by either party is provided not less than 18 months prior to the expiration of the current term. Our material benefits under the BASF Agreement, including our rights to royalty payments on future net sales of such products survive any termination in full force.

In August 2014, we entered into a Collaboration Agreement (the “Capsugel Agreement”) with Capsugel US, LLC relating to the commercial development of astaxanthin products for the consumer health market. Under the terms of the Capsugel Agreement, we agreed to jointly develop consumer health products (“Capsugel Astaxanthin Products”) containing ASTX-1 using Capsugel’s proprietary formulation technology. The Capsugel Agreement provides for the joint administration of activities under a product development plan that will include identifying at least one mutually acceptable third party marketer (a “Marketer”) who will enter into an agreement with Capsugel to further develop, market and distribute Capsugel Astaxanthin Products. The terms of any such agreement with a Marketer are subject to our reasonable consent. The Capsugel Agreement provides that Capsugel shall share revenues with us based on net sales of Capsugel Astaxanthin Products, subject to an administrative fee payable to Capsugel. Capsugel agreed to certain exclusivity obligations with respect to the development and manufacture of Capsugel Astaxanthin Products. Among other matters, Capsugel will perform the development work necessary to formulate, analytically develop and take all other developmental actions necessary or required to develop the Capsugel Astaxanthin Products, and manufacture pre-clinical and clinical batches for use by us and Capsugel. Under the Capsugel Agreement, we will be responsible for, among other matters, the U.S. regulatory process and the regulatory process in non-U.S. jurisdictions to the extent mutually agreed. The term of the Capsugel Agreement is for an initial stated period of three years from the date that a Marketer first offers product for commercial sale under an agreement with Capsugel, subject to specified renewal provisions for additional three year terms and to earlier termination, if commercial milestones that are to be mutually agreed are not achieved. In January 2016, we suspended development of a Capsugel Astaxanthin Product, ASTX-1F, based on certain technical issues which, together with other business and regulatory issues, materially impeded the formulation of ASTX-1F as a commercially viable product for the consumer health market.

Our Strategy

We believe we are well positioned for significant and sustained growth by focusing on additional research and development to commercialize consumer health and pharmaceutical technologies or products utilizing synthetically manufactured astaxanthin (“Cardax Astaxanthin”) and related xanthophyll carotenoids, which deliver nature-identical compounds to the body and reduce inflammation in a multifaceted, quantifiable, and inherently safer manner than steroids or NSAIDS.

Our initial primary focus is astaxanthin technologies. Astaxanthin is a naturally occurring marine compound that has robust anti-oxidant and anti-inflammatory activity with exceptional safety. Astaxanthin is a member of the carotenoid family, which is comprised of organic pigments that are produced in various plants and photosynthetic organisms and consumed by various higher-level organisms; astaxanthin is known for giving salmon and lobster their distinctive red coloration. More specifically, astaxanthin is classified as a xanthophyll, which is an oxygen containing carotenoid (such as lutein, zeaxanthin, and lycophyll), as compared to a carotene, which is non-oxygen containing carotenoid (such as beta-carotene). Research demonstrates that xanthophylls behave differently than carotenes with respect to biological mechanism of action (for example, by spanning and stabilizing biological membranes rather than disrupting membranes), which we believe translates into clinical benefit. Peer-reviewed studies have shown that astaxanthin reduces inflammation, at its source, without the harmful side effects that are common with other anti-inflammatory pharmaceutical products, for example steroids and NSAIDS, including immune system suppression, liver damage, cardiovascular disease risk, and gastrointestinal bleeding.

Astaxanthin has an exceptional safety profile. For example, the FDA found no basis for questioning the safety determination made by Fuji Chemical Industry Co., Ltd. (“Fuji”) in GRAS Notice No. GRN 000294 that *Haematococcus pluvialis* extract containing astaxanthin esters (the primary ingredient in its microalgal astaxanthin consumer health product) is GRAS as a food additive under the intended conditions of use. Other microalgal astaxanthin consumer health manufacturers, including Cyanotech Corporation and Algatechnologies, Ltd., have relied on Fuji’s GRAS designation and self-affirmed their microalgal astaxanthin products as GRAS. The FDA also found no basis for questioning the safety of microalgal astaxanthin products, for use as dietary ingredients in dietary supplements, in several New Dietary Ingredient (NDI) notifications, including RPT 50, RPT 65, RPT 119, RPT 236, RPT 274, and RPT 278. In addition, the FDA amended the color additive regulations under 21 CFR 73 to provide for the safe use of astaxanthin as a color additive to fish feed in 1995 (Federal Register Document No. 95-9178, Docket No. 87C-0316) in response to Color Additive Petition CAP 7C0211 filed by Hoffman-La Roche in 1987, which contained robust non-clinical safety studies with a racemic mixture of synthetic astaxanthin (“DSM Astaxanthin”) now owned by DSM Nutritional Products Ltd. (“DSM”). DSM announced the marketing of DSM Astaxanthin as a consumer health product in 2013 based on its history of use in the food supply as a color additive, the robust non-clinical safety studies that supported the food color additive approval, and additional long term toxicity studies that were submitted to the FDA in 2005. DSM also announced the GRAS self-affirmation of DSM Astaxanthin in 2015. We believe the aforementioned regulatory statuses of various astaxanthin products are indicative of the safety profile of ASTX-1, which is synthesized in the same isomeric form as naturally-occurring, microalgal astaxanthin and comprises 25% of the racemic mixture of synthetic astaxanthin. While our product candidates have not yet been tested in clinical trials and the FDA has not concluded that synthetic astaxanthin, including ASTX-1 or any of our related product candidates, are safe for direct human consumption, we plan to conduct robust non-clinical and clinical studies to lend additional support to the exceptional safety profile of ASTX-1. Unless and until such non-clinical studies, clinical studies, other scientific evidence, GRAS designation, and/or other regulatory filings further support this safety profile, our claim that ASTX-1 is exceptionally safe relies upon:

- widely available astaxanthin research, peer-reviewed studies, and regulatory filings spanning several decades, including (a) FDA GRAS and NDI regulatory filings related to microalgal astaxanthin and other naturally-occurring sources of astaxanthin, (b) FDA color additive petition related to the racemic mixture of synthetic astaxanthin, (c) DSM’s published safety summary supporting the use of DSM Astaxanthin as a dietary ingredient in dietary supplements, and (d) DSM’s GRAS self-affirmation of DSM Astaxanthin;
- human exposure to (a) naturally-occurring astaxanthin in the diet from sources such as wild salmon, trout, and shell-fish, for millennia, (b) the racemic mixture of synthetic astaxanthin, which includes ASTX-1, from sources such as industrially raised salmon, since 1995, and (c) dietary supplements containing naturally-occurring astaxanthin since 1999; and
- our published and unpublished preliminary non-clinical studies utilizing ASTX-1 product candidates.

In humans, astaxanthin has been found in publicly available research studies to lower important inflammatory and metabolic disease measures such as tumor necrosis factor alpha (“TNF- α ”), high-sensitivity complement reactive protein (“hsCRP”), low-density lipoprotein cholesterol (“LDL-C”), apolipoprotein B (“ApoB”), and triglycerides while raising adiponectin and high-density lipoprotein cholesterol (“HDL-C”). Astaxanthin has also positively affected markers of oxidative stress in humans including isoprostanes, malondialdehyde (“MDA”), total anti-oxidant capacity (“TAC”), and superoxide dismutase (“SOD”). Astaxanthin and related esters have demonstrated efficacy in models of inflammatory-mediated disease including reduction of TNF- α levels equivalent to a steroid, reduction of liver enzymes and liver histological damage, reduction of cholesterol levels, reduction of elevated triglycerides, decrease of atheroma formation, reduction of oxidized-LDL levels, reduction in blood clot formation with no increase in bleeding, and decrease in myocardial tissue damage following experimentally-induced myocardial infarction.

We believe that the current manufacturing capability of astaxanthin producers utilizing microalgal or other natural manufacturing processes may not satisfy the growing demand for astaxanthin and there will be a need for the synthetic production of nature-identical astaxanthin with pharmaceutical-grade purity at economical costs.

We plan to promote scientific understanding of astaxanthin through several strategies, including:

- sponsoring relevant scientific and medical conferences and presenting or facilitating the presentation of appropriate scientific data to the thousands of physicians and key opinion leaders and the patient groups who typically attend these conferences;
- advancing direct-to-consumer internet and social media marketing;
- continuing to support scientific research and publication of peer-reviewed papers; we have collaborated on more than 50 such papers, including 10 papers published in *The American Journal of Cardiology*, that have noted the benefits and safety of astaxanthin in the treatment of diseases that have inflammation as a common cause;
- convening scientific advisory board meetings to review existing and planned scientific research, with scientific advisory board members including, but not limited to, persons previously engaged by our predecessors, in the areas of osteoarthritis, cardiovascular disease, and liver disease; and
- conducting human clinical trials.

While the FDA does not require human clinical trials for consumer health products, and under applicable regulations we are not permitted to make claims for treatment of diseases for any consumer health products, we believe that positive results from a Phase I human clinical trial and a suite of approximately three to five Phase II human clinical trials in select disease areas of major unmet medical need would significantly raise scientific and consumer awareness that would promote consumer health sales and advance our pharmaceutical development program.

Our Consumer Health Program

In July 2015, we announced that our Cardax Astaxanthin product candidates demonstrated superior plasma exposure versus microalgal astaxanthin in a monkey study. The single-dose pharmacokinetic study compared the plasma exposure of our Cardax Astaxanthin product candidates, ASTX-1F and CDX-085, to microalgal astaxanthin, the predominate astaxanthin consumer health product form on the market. The study was conducted by top-tier contract research organizations.

ASTX-1F, a proprietary formulation of nature-identical astaxanthin, demonstrated more than three (3) times higher plasma exposure than microalgal astaxanthin in the study. ASTX-1F has approximately the same astaxanthin content per unit weight of the dietary ingredient as microalgal astaxanthin. The combination of ASTX-1F's higher plasma exposure and similar astaxanthin content translates into more than three (3) times the relative strength per unit weight of the dietary ingredient compared to microalgal astaxanthin and could reduce the size/number of capsules or tablets required to achieve equivalent circulating levels of astaxanthin.

CDX-085, our patented pure ester of nature-identical astaxanthin, demonstrated more than two and one-half (2-1/2) times higher plasma exposure than microalgal astaxanthin in the study. CDX-085 has approximately seven (7) times higher astaxanthin content per unit weight of the dietary ingredient than microalgal astaxanthin. The combination of CDX-085's higher plasma exposure and higher astaxanthin content translates into more than seventeen (17) times the relative strength per unit weight of the dietary ingredient compared to microalgal astaxanthin and could reduce the size/number of capsules or tablets required to achieve equivalent circulating levels of astaxanthin.

In January 2016, we decided to suspend development of ASTX-1F because we were informed by our principal ASTX-1F development collaborator, Capsugel, that it determined there were certain technical issues which, together with other business and regulatory issues, materially impeded the formulation of ASTX-1F as a commercially viable product for the consumer health market. Capsugel had previously agreed to use its commercially reasonable efforts to develop formulations and take other commercialization steps related to ASTX-1F. Consequently, we determined that our proposed ASTX-1F product candidate would not be commercially viable without further extensive development, which may likely render this product too costly for commercial viability. We believe that the technical issues presented with the ASTX-1F product candidate will not be material in the commercial development of our CDX-085 product candidate.

We believe that our resources should be used to continue the development of our CDX-085 product candidate and, on a limited basis, explore development of astaxanthin formulations with manufacturers that may be able to produce product candidates for the consumer health market on a commercially viable basis. We may consider leveraging our scientific experience and relationships in the scientific community to market consumer health products utilizing commercial-ready astaxanthin dietary ingredients in order to start generating cash flow and building a market for Cardax Astaxanthin products.

Our Planned Pharmaceutical Program

We believe that a pharmaceutical program will increase our revenue opportunities. A pharmaceutical product would enable the delivery of astaxanthin with an FDA approved over-the-counter drug ("OTC") label for disease treatment at consumer-appropriate doses and/or an FDA approved prescription drug ("Rx") label for disease treatment at physician-recommended doses, and should support increased market penetration. We have patents covering pharmaceutical compositions of astaxanthin esters, allowing us to transition an astaxanthin consumer health product into a pharmaceutical product following requisite clinical trials and FDA approval.

We plan to raise additional capital or enter into a strategic collaboration to pursue clinical development of Cardax Astaxanthin. We may choose to undertake the following actions upon certain events including if Cardax Astaxanthin obtains all applicable regulatory approvals or designations necessary for marketing as a consumer health product:

- file an Investigational New Drug application (“IND”) with the FDA;
- conduct a Phase I human clinical trial to expand clinical dosing of Cardax Astaxanthin beyond that of the approved consumer health dose of Cardax Astaxanthin; and
- conduct three to five Phase II human clinical trials, with a range of doses in areas of major consumer health and/or unmet medical need.

This strategy would offer more than one potential avenue of development and mitigate the risks, including “binary events,” associated with single indication development. We may appropriately augment our management team to pursue this strategy.

If any of the lower doses of Cardax Astaxanthin tested in our planned Phase II human clinical trials demonstrate robust safety and efficacy in an area of major consumer health need and are less than or equal to the currently approved consumer health dose of Cardax Astaxanthin, we may decide to conduct pivotal Phase III trials and file a 505(b)(1) or 505(b)(2) New Drug Application (“NDA”) to obtain an OTC label for “low-dose” Cardax Astaxanthin (“OTC-ASTX”). Post-approval clinical studies could also be conducted to expand the label and/or dose. OTC-ASTX may be initially targeted for light-to-moderate osteoarthritis or the onset of other inflammatory disorders. Marketing and distribution of OTC-ASTX could be conducted through global consumer health companies or global pharmaceutical companies under license from Cardax, or through any other strategic relationship that we find acceptable.

If any of the higher doses of Cardax Astaxanthin tested in any such Phase II human clinical trials demonstrate robust safety and efficacy in an area of major unmet medical need, then we may decide to conduct pivotal Phase III trials and file a 505(b)(1) NDA to obtain an Rx label for “high-dose” Cardax Astaxanthin (“Rx-ASTX”). Rx-ASTX may be initially targeted for moderate-to-severe osteoarthritis, rheumatoid arthritis, cognitive decline, metabolic disease, dyslipidemia, or diabetes. Post-approval clinical studies could also be conducted to expand the initial label. Other potential indications driven by oxidative stress and inflammation include, but are not limited to, hepatitis, atherosclerosis, and recurrent thrombosis. Marketing and distribution of Rx-ASTX could be conducted through global pharmaceutical companies under license from Cardax.

Astaxanthin Disease Applications, Mechanism of Action, and Safety

Chronic inflammation and oxidative stress drive “inflammation syndrome” and “metabolic syndrome,” which are manifested in the form of multifactorial symptomatic disease, and redound to the treatment of many apparently distinct yet interconnected disorders at their inflammatory source with a safe and effective product such as astaxanthin.

Cardax Astaxanthin products deliver astaxanthin to the circulation. In the case of CDX-085, the novel astaxanthin ester cleaves in the gut and delivers non-esterified astaxanthin to the circulation. Microalgal astaxanthin consumer health products are comprised of a mixture of naturally occurring astaxanthin esters that also cleave in the gut and deliver non-esterified astaxanthin to the circulation. Non-esterified astaxanthin, as can be delivered by Cardax Astaxanthin, microalgal astaxanthin products, or other astaxanthin products, can be measured in blood and tissues and is generally recognized to be responsible for the anti-inflammatory and anti-oxidant effects and exceptional safety found in animals and humans following administration of astaxanthin products. For the purpose of discussing astaxanthin disease applications, mechanism of action, safety, and supporting scientific studies, whether examining non-esterified astaxanthin, naturally occurring astaxanthin esters, or novel astaxanthin esters, we refer to these products as “astaxanthin.”

Astaxanthin for Arthritis

We believe that there is a large potential market for osteoarthritis treatment. We estimate that there are more than 150 million people in developed nations that suffer from osteoarthritis who have the financial ability to pay for treatment through astaxanthin products. Assuming \$1 per day for treatment, the potential market could exceed \$50 billion annually. Recent expenditures for treatment of arthritis are also substantial. The Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services (the “CDC”) report that the amount of direct medical expenditures in the United States for arthritis and other rheumatic conditions for 2003 was \$80.8 billion. Drugs.com noted that aggregate U.S. sales of the top three injected TNF- α inhibitors totaled more than \$12 billion in 2012. New oral anti-inflammatory drugs may also be approved, further increasing the amount expended for drug treatment. We expect that these drugs will be based on steroid, NSAID, or enzyme/receptor technologies that could pose significant side effects when administered chronically. In contrast, astaxanthin, at very low doses, reduces TNF- α in humans. In non-human tests, astaxanthin reduces TNF- α equivalent to a corticosteroid—considered to be the most potent of the anti-inflammatory compounds—as well as other important mediators of inflammation including hsCRP, prostaglandin E2 (“PGE-2”), interleukin 6 (“IL-6”), nuclear factor kappa B (“NF- κ B”), and nitric oxide (“NO”). We believe that no evidence of the immunosuppressive effects of steroids or TNF- α inhibitors has been seen in multiple animal or human studies using astaxanthin. In fact, in animals, astaxanthin administration is statistically significantly associated with fewer infections.

Astaxanthin for Cognitive Decline

According to the CDC, the number of U.S. adults aged 65 or older will more than double by 2030. As the percentage of elderly in the population continues to increase, the prevalence of diseases resulting in cognitive decline may be also expected to increase. While the underlying cause of cognitive decline still remains to be fully elucidated, many studies support the important pathophysiological role of oxidative stress and inflammation, particularly in both Alzheimer's disease and Parkinson's disease. Further, epidemiological studies support a relationship between brain carotenoids (i.e., a class of related natural compounds including astaxanthin) and cognitive performance. Measurable amounts of carotenoids have also been found in the human brain and are reported to be significantly lower in the brain of Alzheimer's disease patients. Most importantly, a recently conducted, randomized, double-blind, placebo-controlled human clinical trial supported the potential for astaxanthin to improve cognitive function in an elderly population afflicted with age-related forgetfulness. The trial was conducted with astaxanthin doses comparable to current consumer health product doses. The development of an astaxanthin based anti-inflammatory approach to aid in cognitive decline represents potential treatment for an expanding population with few options to help slow progression or delay onset of these diseases.

Astaxanthin for Metabolic Syndrome

Metabolic syndrome is a combination of medical disorders that together increase the risk of developing cardiovascular disease, diabetes, and liver disease. Several pathophysiological features define metabolic syndrome including central obesity, increased triglyceride levels, decreased HDL-C levels, elevated blood pressure, and increased fasting glucose levels. In humans, astaxanthin has been shown to significantly lower triglycerides and increase HDL-C levels. Similarly, in animal models of disease, astaxanthin administration significantly decreased blood pressure, increased HDL-C levels, lowered triglycerides, and decreased fasting glucose levels. In addition, decreased levels of the metabolic regulator adiponectin are associated with dysfunction of critical signaling pathways that control glucose production and uptake, triglyceride production and distribution, and mitochondrial biogenesis and function. Astaxanthin has been shown in human and animal studies to significantly increase levels of adiponectin with the inference that restoration of adiponectin function is key to remediation of metabolic syndrome physiology. These studies underscore the potential for astaxanthin treatment to ameliorate the majority of physiological measures defining metabolic syndrome and thereby decrease the risk of ensuing cardiovascular disease, diabetes, and liver disease.

Astaxanthin for Triglyceride Reduction

Certain therapies for the reduction of triglycerides have issues of safety or convenience. Astaxanthin, however, has been shown to reduce elevated triglycerides in a multi-faceted, quantifiable, and safer manner. Fibric acid derivatives exhibit risks of adverse effects when used in combination with statins. Newer drugs such as purified derivatives of the omega-3 fatty acids must be taken at very high doses and some increase LDL-C concomitant with induced liver stress. In contrast, astaxanthin not only shows significant triglyceride and LDL-C lowering capability, at much lower, more manageable doses, but it also lowers key markers of inflammation such as TNF- α and raises HDL-C and adiponectin in humans.

Astaxanthin for Type 2 Diabetes

Type 2 diabetes mellitus ("T2DM") is a metabolic disorder characterized by chronic high blood glucose in the context of insulin resistance and relative insulin deficiency. The rate of T2DM has increased materially over the last several decades in parallel with obesity. Chronic inflammation and oxidative stress, which influence intracellular signaling pathways critical to normal metabolic function, have been shown to play an important role in the pathology of T2DM. Drugs including the highly prescribed Metformin are presumed to act via pathways that regulate glucose production, insulin signaling, and mitochondrial functionality, including AMPK (adiponectin pathway) and PI-3/AKT (insulin receptor pathway). Astaxanthin has also been shown to upregulate adiponectin levels in humans and animal models of metabolic dysfunction and thereby restore AMPK pathway functionality. Additionally, astaxanthin has increased insulin levels, decreased glucose levels, and elevated measures of insulin sensitivity in several animal models of disease. Importantly, signaling pathways that regulate glucose and insulin signaling (PI-3/AKT) are often dysregulated and inhibited by oxidative stress and inflammation. Astaxanthin has been shown to upregulate and normalize these insulin and glucose pathways in animal models resulting in restoration of metabolic homeostasis. The evidence to date supports the potential for astaxanthin to ameliorate causes and symptoms of T2DM in humans.

Astaxanthin for Hepatic Disease

While hepatitis C virus and hepatitis B virus related liver disease continues to be of significant health concern, several metabolism-linked liver diseases currently have significant prevalence including fatty liver disease (“FLD”), non-alcoholic steatohepatitis (“NASH”), and alcoholic steatohepatitis (“ASH”). NASH is the inflammatory progression of FLD and threatens to be the leading indication for liver transplantation in the United States. Chronic oxidative stress and inflammation play an important physiological role in the initiation and progression of NASH and ASH, a position supported by the fact that the anti-oxidant vitamin E has recently been shown to decrease liver enzyme levels and, importantly, diminish biopsy-determined liver pathology in the PIVENS trial, underscoring the importance of oxidative stress in NASH pathophysiology. Astaxanthin, which is normally processed and stored in the liver, has been shown in an animal model of liver disease to decrease elevated liver enzymes and diminish histological pathology. Current clinical treatments for NASH include the thiazolidinediones (pioglitazone and rosiglitazone) that appear to act via stimulation of peroxisome proliferator-activated receptor gamma (“PPAR- γ ”) driven pathways to influence lipid and glucose metabolism. In cell studies, both vitamin E and astaxanthin also exhibit PPAR- γ activating capacities. The importance of chronic inflammation and oxidative stress on NASH and ASH pathological progression underscores the potential influence of astaxanthin to ameliorate liver disease in humans.

Astaxanthin for Atherosclerosis

Atherosclerosis is a syndrome affecting arterial blood vessels resulting from chronic inflammation and the accumulation of macrophages and LDL without adequate removal of fats and cholesterol by HDL. In addition to chronic inflammation, chronic oxidative and nitrosative stress also play a significant role in the disease via oxidation and dysregulation of LDL and HDL particles. Astaxanthin has been shown to significantly decrease LDL-C and ApoB levels, increase HDL-C, and decrease TNF- α in humans. Likewise, astaxanthin has been shown to significantly decrease total cholesterol and LDL-C levels and increased HDL-C levels in several animal models of disease. Astaxanthin has been shown to decrease atheroma formation in a diet-driven atherogenesis animal model as well as decrease several measures of LDL oxidation. The effect of astaxanthin on HDL and LDL functionality is understandable because astaxanthin is naturally located within HDL and LDL particles for distribution systemically. An important source of oxidative stress affecting HDL and LDL particles in humans is myeloperoxidase (“MPO”) and astaxanthin has been shown to significantly decrease MPO activity in animals. Astaxanthin was also shown in a cell-based study to increase cholesterol efflux from macrophages, a function that would drastically aid in reduction of atherosclerotic disease. These observations underscore the potential importance of astaxanthin in treatment of atherosclerosis and related cardiovascular diseases.

Astaxanthin for Thrombosis

Rethrombosis is a major risk for people who have had acute coronary syndrome or an ischemic stroke. The goal of therapy following thrombosis is to maintain arterial patency and to preserve the area of reduced perfusion in the heart or the brain. Following a thrombotic stroke, for example, the re-occlusion, or rethrombosis rate, is high, estimated at 30% overall in the first 30 days. A majority of the re-occlusive events occur within the initial 7-10 days post-treatment. While therapies targeting stroke and in particular brain salvage (i.e., neuroprotection) have had limited clinical success, we believe that prevention of the reformation of blood clots, or rethrombosis, is a novel and relatively efficient pathway to demonstrate feasibility for human use and to an eventual FDA approval for this indication. Lysing blood clots has already proven helpful with tissue plasminogen activator (“tPA”) and other thrombolytic agents, and prevention of rethrombosis can be measured in a statistically significant and clinically meaningful way. In several animal studies of thrombosis and rethrombosis, astaxanthin administration has been shown to demonstrate robust efficacy with no change in bleeding times.

Consistent with other astaxanthin disease applications, oxidative stress and inflammation play major roles in the pathophysiology of rethrombosis. While we plan to focus initially on arthritis, cognitive decline, and metabolic dysfunction, we remain very interested in areas such as rethrombosis and related platelet aggregation following an ischemic stroke, where animal models have been particularly predictive of human efficacy.

Astaxanthin Mechanism of Action

Following oral administration of astaxanthin and intestinal uptake, astaxanthin is delivered initially to the liver via chylomicrons and subsequently distributed to tissues throughout the body via plasma lipoprotein particles including very low-density lipoprotein (“VLDL”), HDL, and LDL. Once in the cell, astaxanthin accumulates within various organelles including nuclear, endoplasmic reticulum (“ER”), and mitochondrial membranes. Localization within mitochondria is highly controlled by the cell and allows astaxanthin to uniquely regulate oxidative and nitrosative stress in a privileged location critical to normal metabolic function and often at the heart of metabolic dysfunction and aging. Due to its chemical structure, astaxanthin completely spans the lipid component of cell membranes, facilitating its biphasic (aqueous and lipid) anti-oxidant functions. In support of the unique property of astaxanthin, one study examined X-ray diffraction profiles of five structurally related anti-oxidants embedded in a lipid matrix and demonstrated that each oriented differently with only astaxanthin traversing the lipid, potentially explaining in part why other well-known anti-oxidants, including beta-carotene, vitamin C, and vitamin E, have not achieved greater clinical success. In addition to mitochondrial influence, astaxanthin’s aqueous and lipid anti-oxidant functions have the capacity to influence intracellular inflammatory and metabolic pathway signaling because many important intracellular pathways are directly modulated by inflammatory and oxidative stress mediators. In support of strong anti-oxidant function within the body, astaxanthin administration has been shown to demonstrate statistically significant anti-oxidant capacity in humans as measured by decreased isoprostanes, decreased MDA levels, increased TAC, and increased SOD, as well as decreased lipid peroxidation. Likewise, numerous animal studies have supported the extensive and powerful anti-oxidant capacity of astaxanthin *in vivo*. Many studies support the strong influence of astaxanthin on mitochondrial functionality, as well as inflammatory and metabolic intracellular signaling in animals and in cell-based models.

Astaxanthin Anti-Inflammatory Comparison to Steroids and NSAIDs

Glucocorticoid steroids and NSAIDs act mechanistically to trans-repress and reduce many inflammatory pathways/mediators including but not restricted to tumor necrosis factor alpha (TNF- α), interleukin one beta (IL-1 β), nuclear factor kappa B (NF- κ B), interleukin six (IL-6), prostaglandin E2 (PGE-2), monocyte chemoattractant protein one (MCP-1), extracellular signal-regulated kinase (ERK), c-jun N-terminal kinase (JNK), inducible nitric oxide synthase (iNOS) and cyclooxygenase 2 (COX-2). Astaxanthin has been shown in humans, animal models and cell systems to act upon and inhibit/reduce many of the same inflammatory mediators affected by glucocorticoid steroids and NSAIDs. Although Cardax’s particular astaxanthin product candidates have not been tested in human clinical studies, the following statements are based on relevant data derived from human/animal/cell system studies conducted using microalgal and synthetic astaxanthin sources. Importantly, administration of astaxanthin to humans reduced the inflammatory mediator TNF- α in an open label study and decreased C-Reactive Protein (CRP) in a double-blind, placebo-controlled study. More specifically, in animal models and cell culture systems, administration of astaxanthin reduced several markers of inflammation overlapping with glucocorticoid steroid targets. In particular, astaxanthin has been shown to significantly reduce TNF- α , IL-1 β , NF- κ B, IL-6, PGE-2, MCP-1, ERK, JNK, iNOS, and COX-2. In one comparative animal study, astaxanthin and prednisolone showed quantitatively equivalent efficacy by significantly reducing TNF- α and PGE-2 levels an equal amount when administered at equivalent doses.

Safety

Safety is a critical aspect of drug development in the current regulatory environment. Many anti-inflammatory drugs target highly specific biological enzymes or receptors such as cyclooxygenase 2 (“COX-2”), TNF- α , and C-C chemokine receptor type 2 (“CCR2”). While these natural targets play a significant role in inflammation, they are also critical components of other important biological pathways. With chronic use of most anti-inflammatory drugs, these pathways may not function normally, resulting in adverse side effects. Also, these treatments often negatively affect other crucial biological systems, creating additional off-target side effects.

In contrast, astaxanthin safely reduces inflammation at its source, in that it:

- localizes in the plasma, mitochondrial, and nuclear membranes;
- scavenges or quenches the unwanted initiators and effectors of inflammation—reactive oxygen (“ROS”) and nitrogen species (“RNS”); and
- demonstrates no evidence of the immunosuppressive effects of steroids or TNF- α inhibitors or off-target effects (e.g., receptor or pathway).

Our Other Programs

We have two other anti-inflammatory programs with potential applications in large markets that are in development: zeaxanthin esters for macular degeneration and hepatic disease; and lycophyll esters for prostate disease. Both of these product platforms have potential to be developed first as consumer health products and later as pharmaceuticals. We have used a limited amount of synthetic zeaxanthin in our preliminary research and development efforts. We plan additional research and development to select the optimal zeaxanthin esters for consumer health and/or pharmaceutical development through our own capabilities or through a strategic alliance or a manufacturing agreement. We have produced synthetic lycophyll and we plan to conduct additional research and development to first increase our production capabilities of lycophyll and then to select the optimal lycophyll esters for consumer health and/or pharmaceutical development through our own capabilities or through a strategic alliance or a manufacturing agreement. To date, we have not commercialized any of these technologies.

Research and Development

Our research and development program is presently comprised of employees, consultants, including regulatory, scientific, and medical professionals, and third-party collaborators or contract organizations, including academic institutions, contract research organizations, and contract manufacturing organizations. We utilized dedicated internal synthetic chemistry, biology, and bioanalytical chemistry laboratories and a research and development staff to conduct discovery stage synthesis of product candidates (with transfer of materials and/or methods for additional process development and/or testing), *in vitro* testing of product candidates and related components to elucidate the mechanism of action, and analysis of biological samples from internal research and/or contract organizations to detect and quantify levels of product candidates and related components following administration of product in various studies. Our research and development staff has also worked with other professionals to identify, contract and transfer materials and methods, and oversee research and manufacturing by contract organizations. Contract organizations provide us with access to larger scale manufacturing, animal studies of disease, pharmacokinetics, and toxicity, and analysis that would not otherwise be available to us without significant expense. We anticipate that the majority of our research and development will be conducted by contract organizations with direction and oversight by our current internal research and development personnel, including three Ph.D. scientists, two Ph.D. scientists/executives, one operational executive, and one M.D. consultant.

In addition to conducting or overseeing research and development activities, our research and development personnel analyze and interpret other research on astaxanthin, as well as related compounds, competing products, applicable disease pathology, and industry trends. In the United States National Library of Medicine's online repository, PubMed.gov, there are more than 1,000 peer-reviewed journal articles that reference astaxanthin in the title or abstract, over 300 of which were published in the last three years, with the vast majority published by organizations and researchers that are not affiliated with us. This type of "open-source" research has served to significantly advance the understanding of astaxanthin, and has also presented our research and development personnel with the critical task of keeping up-to-date on all of the latest research and interpreting and integrating the findings with our research and that of others in order to serve as the preeminent thought leaders on astaxanthin's mechanism of action and its application in biological systems and disease areas.

Our research and development expenditures totaled \$491,829 and \$1,160,771 for the years ended December 31, 2015 and 2014. These expenditures primarily reflect the compensation of our research and development personnel.

Government Regulation

Most aspects of our business are subject to some degree of government regulation. For some of our products, government regulation is significant and, in general, there appears to be a trend toward more stringent regulation throughout the world, as well as global harmonization of various regulatory requirements. We expect to devote significant time, effort and expense to address the extensive government and regulatory requirements applicable to our business. We believe that we are no more or less adversely affected by existing government regulations than our competitors.

FDA Regulation

Pharmaceutical companies must comply with comprehensive regulation by the FDA and other regulatory agencies in the United States and comparable authorities in other countries. While the FDA does not require human clinical trials for consumer health products, we may conduct Phase I, Phase II, and/or Phase III clinical trials with our products.

We must obtain regulatory approvals by the FDA and, to the extent we have any international distribution of our products, foreign government agencies prior to human clinical testing and commercialization of any pharmaceutical product and for post-approval clinical studies for additional indications in approved drugs. We anticipate that any pharmaceutical product candidate will be subject to rigorous preclinical and clinical testing and pre-market approval procedures by the FDA and similar health authorities in foreign countries to the extent applicable. The extent to which our products are regulated by the FDA, and the designations applicable to our products, will depend upon the types of products we ultimately develop. We are currently evaluating other product developments or technologies to pursue and cannot predict, during this stage of our development, the scope of FDA or other agency regulation to which we or our products and technologies will be subject. Various federal statutes and regulations also govern or influence the preclinical and clinical testing, record-keeping, approval, labeling, manufacture, quality, shipping, distribution, storage, marketing and promotion, export and reimbursement of products and product candidates.

The steps ordinarily required before a drug product may be marketed in the United States include:

- preclinical studies;
- submission to the FDA of an IND, which must become effective before human clinical trials may commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate in the desired indication for use;
- submission of a NDA to the FDA, together with payment of a substantial user fee; and
- FDA approval of the NDA, including inspection and approval of the product manufacturing facility and select sites at which human clinical trials were conducted.

Preclinical trials typically involve laboratory evaluation of product candidate chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of each product candidate. The results of preclinical trials are submitted to the FDA as part of an IND and are reviewed by the FDA before the commencement of clinical trials. Unless the FDA objects to an IND, the IND will become effective 30 days following its receipt by the FDA. Submission of an IND may not result in FDA clearance to commence clinical trials, and the FDA's failure to object to an IND does not guarantee FDA approval of a marketing application.

Clinical trials involve the administration of the product candidate to humans under the supervision of a qualified principal investigator. In the United States, clinical trials must be conducted in accordance with Good Clinical Practices under protocols submitted to the FDA as part of the IND. In addition, each clinical trial must be approved and conducted under the auspices of an institutional review board and with the patient's informed consent. We would be subject to similar protocols and similar regulatory considerations if we conduct clinical trials outside the United States.

The goal of Phase I clinical trials is to establish initial data about safety and tolerability of the product candidate in humans. The investigators seek to evaluate the effects of various dosages and to establish an optimal dosage level and schedule.

The goal of Phase II clinical trials is to provide evidence about the desired therapeutic efficacy of the product candidate in limited studies with small numbers of carefully selected subjects. Investigators also gather additional safety data.

Phase III clinical trials consist of expanded, large-scale, multi-center studies in the target patient population. This phase further tests the product's effectiveness, monitors side effects, and, in some cases, compares the product's effects to a standard treatment, if one is already available. Phase III trials are designed to more rigorously test the efficacy of a product candidate and are normally randomized, double-blinded, and placebo-controlled. Phase III trials are typically monitored by an independent data monitoring committee, or DMC, which periodically reviews data as a trial progresses. A DMC may recommend that a trial be stopped before completion for a number of reasons including safety concerns, patient benefit or futility.

Data obtained from this development program are submitted as part of a NDA to the FDA and possibly to corresponding agencies in other countries for review. The NDA requires agency approval prior to marketing in the relevant country. Extensive regulations define the form, content and methods of gathering, compiling and analyzing the product candidate's safety and efficacy data.

The process of obtaining regulatory approval can be costly, time consuming and subject to unanticipated delays. Regulatory agencies may refuse to approve an application if they believe that applicable regulatory criteria are not satisfied and may also require additional testing for safety and efficacy and/or post-marketing surveillance or other ongoing requirements for post-marketing studies. In some instances, regulatory approval may be granted with the condition that confirmatory Phase IV clinical trials are carried out, and if these trials do not confirm the results of previous studies, regulatory approval for marketing may be withdrawn. Moreover, each regulatory approval of a product is limited to specific indications. The FDA or other regulatory authorities may approve only limited label information for the product. The label information describes the indications and methods of use for which the product is authorized, may include Risk Evaluation and Mitigation Strategies and, if overly restrictive, may limit a sponsor's ability to successfully market the product. Regulatory agencies routinely revise or issue new regulations, which can affect and delay regulatory approval of product candidates.

Furthermore, pharmaceutical manufacturing processes must conform to current Good Manufacturing Practices, or cGMPs. Manufacturers, including a drug sponsor's third-party contract manufacturers, must expend time, money and effort in the areas of production, quality control and quality assurance, including compliance with stringent record-keeping requirements. Manufacturing establishments are subject to periodic inspections by the FDA or other health authorities, in order to assess, among other things, compliance with cGMP. Before approval of the initiation of commercial manufacturing processes, the FDA will usually perform a preapproval inspection of the facility to determine its compliance with cGMP and other rules and regulations. In addition, foreign manufacturing establishments must also comply with cGMPs in order to supply products for use in the United States, and are subject to periodic inspection by the FDA or by regulatory authorities in certain countries under reciprocal agreements with the FDA. Manufacturing processes and facilities for pharmaceutical products are highly regulated. Regulatory authorities may choose not to certify or may impose restrictions, or even shut down existing manufacturing facilities that they determine are non-compliant.

FDA GRAS Determination

“GRAS” is an acronym for the phrase “generally recognized as safe,” which the FDA utilizes to describe those substances that, in the generally recognized opinion of the scientific community, will not be harmful to consumers, provided the substance is used as intended. According to applicable FDA regulations, any substance that is intentionally added to food is a food additive, which is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the “FD&C Act”), and FDA’s implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food. General recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information. General recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

Manufacturers of GRAS substances may provide the FDA with a notification of GRAS determination, which includes a description of the substance, the applicable conditions of use, and an explanation of how the substance was determined to be safe. Upon review of such a notification, the FDA may respond with a “no questions” position, whereby the manufacturer’s determination that a product is GRAS for its intended purposes is affirmed. Alternatively, manufacturers may elect to “self-affirm” a given substance as GRAS without FDA notification but should retain all applicable safety data used for GRAS determination in the case of FDA inquiry.

Synthetic copies of naturally-occurring dietary ingredients or related components do not qualify as dietary ingredients under the FD&C Act, but substances that have been affirmed by the FDA as GRAS, self-affirmed as GRAS, or approved as direct food additives in the U.S. may be marketed as dietary ingredients, subject to FDA regulations for dietary ingredients. We expect that nature-identical synthetic astaxanthin would be required to be designated as GRAS before being marketed as a dietary ingredient and that there would not be any material impediment to obtaining such designation by any manufacturer or distributor of synthetic astaxanthin products, primarily because naturally occurring astaxanthin and the racemic mixture of synthetic astaxanthin have already been designated as GRAS.

FDA NDI Notification

The Dietary Supplement Health and Education Act of 1994 (the “DSHEA”) (Pub. L. 103-417) was signed into law on October 25, 1994 and amended the FD&C Act by adding: (i) section 201(ff) (21 U.S.C. 321(ff)), which defines the term “dietary supplement”, and (ii) section 413 (21 U.S.C. 350b), which defines the term “new dietary ingredient” (“NDI”) and requires the manufacturer or distributor of an NDI, or of the dietary supplement that contains the NDI, to submit a premarket notification to FDA at least 75 days before introducing/delivering the supplement into interstate commerce, unless the NDI and any other dietary ingredients in the dietary supplement have been present in the food supply without chemical alteration (21 U.S.C. 350b(a)(1)). The NDI notification must contain applicable information, including history of use and citations to published articles, from which the manufacturer or distributor of the NDI or dietary supplement has concluded that the dietary supplement containing the NDI will be reasonably expected to be safe under the conditions of its intended use. NDI notifications are not required for the marketing of approved food additives or GRAS substances as NDIs unless the dietary ingredient has been chemically altered or the intake level of the dietary ingredient under its intended conditions of use is higher than the intake level approved in the food additive regulation or designated as GRAS. We expect that an NDI notification would be submitted to the FDA prior to marketing nature-identical synthetic astaxanthin as a dietary ingredient in dietary supplements at levels above the GRAS intake or with chemical alteration.

Hawaii Tax Credit

For tax years 2006 to 2010, our predecessor received an aggregate amount of \$1,262,117 in refundable tax credits from the State of Hawaii – Department of Taxation in connection with qualified research expenditures in the State of Hawaii. The Hawaii Tax Credit for Research Activities (“HTCRA”) was intended to encourage taxpayers to design, develop, and/or improve products, processes, techniques, formulas or software and intended to reward programs that pursue innovation in the State of Hawaii. The HTCRA was discontinued by the State of Hawaii for tax years 2011 and 2012, but was made available again starting in tax year 2013 with certain modifications to the qualification and credit calculations.

Federal Research and Development Tax Credit

In January 2013, the President of the United States signed into law the American Taxpayer Relief Act of 2012, which extended the United States research and development tax credit (the “Research Credit”) under Section 41 of the Internal Revenue Code of 1986, as amended, for tax years 2012 and 2013, as well as other provisions. The Research Credit provided taxpayers, such as the Company with a specified tax credit for qualified research activities, including those conducted by us. The Research Credit expired on December 31, 2013.

Federal Qualified Therapeutic Development Project Credit

In 2010, our predecessor received \$244,479 as a refundable Qualifying Therapeutic Discovery Project (“QTDP”) tax credit from the federal government. The QTDP Program was a tax benefit (a tax credit or grant) to small firms that showed significant potential to produce new and cost-saving therapies, support United States jobs, and increase United States competitiveness. The QTDP Program was part of the Patient Protection and Affordable Care Act of 2010, and was included in Section 48D of the Internal Revenue Code of 1986, as amended. To provide an immediate boost to United States biomedical research, the credit or grant was available for qualified investments made, or to be made, in tax years 2009 and 2010.

Other Regulations

Pharmaceutical companies, including us, are subject to various federal and state laws pertaining to healthcare “fraud and abuse,” including anti-kickback and false claims laws. The Federal Anti-kickback Statute makes it illegal for any person, including a prescription drug manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, offer, receive or pay any remuneration, directly or indirectly, in exchange for, or to induce, the referral of business, including the purchase, order or prescription of a particular drug, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. Some of the state prohibitions apply to referral of patients for healthcare services reimbursed by any source, not only the Medicare and Medicaid programs.

In the course of practicing medicine, physicians may legally prescribe FDA approved drugs for an indication that has not been approved by the FDA and which, therefore, is not described in the product’s approved labeling, so-called “off-label use.” The FDA does not ordinarily regulate the behavior of physicians in their choice of treatments. The FDA and other governmental agencies do, however, restrict communications on the subject of off-label use by a manufacturer or those acting on behalf of a manufacturer. Companies may not promote FDA-approved drugs for off-label uses. The FDA and other governmental agencies do permit a manufacturer (and those acting on its behalf) to engage in some limited, non-misleading, non-promotional exchanges of scientific information regarding unapproved indications. The United States False Claims Act prohibits, among other things, anyone from knowingly and willfully presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including imprisonment, fines and civil monetary penalties, as well as possible exclusion from federal health care programs (including Medicare and Medicaid). In addition, under this and other applicable laws, such as the Food, Drug and Cosmetic Act, there is an ability for private individuals to bring similar actions. Further, there is an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the law.

We are subject to various laws and regulations regarding laboratory practices and the experimental use of animals in connection with our research. In each of these areas, as above, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to suspend or delay issuance of approvals, seize or recall products, withdraw approvals, enjoin violations and institute criminal prosecution, any one or more of which could have a material adverse effect upon our business, financial condition and results of operations.

We must comply with regulations under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act and other federal, state and local regulations. We are subject to federal, state and local laws and regulations governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain hazardous or potentially hazardous materials. We may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the controlled use of hazardous materials, including, but not limited to, certain hazardous chemicals.

Our activities are also potentially subject to federal and state consumer protection and unfair competition laws. We are also subject to the United States Foreign Corrupt Practices Act, or the FCPA, which prohibits companies and individuals from engaging in specified activities to obtain or retain business or to influence a person working in an official capacity. Under the FCPA, it is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, governmental staff members, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In addition, federal and state laws protect the confidentiality of certain health information, in particular, individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and Human Services promulgated health information privacy and security rules under the Health Insurance Portability and Accountability Act of 1996. In addition, many state laws apply to the use and disclosure of health information.

Competition

The industry in which we intend to compete is subject to intense competition. We believe that our ability to compete will be dependent in large part upon our ability to continually enhance and improve our products and technologies. In order to do so, we plan to effectively utilize and expand our research and development capabilities. Competition is based primarily on scientific and technological superiority, technical support, availability of patent protection, protection of trade secrets, access to adequate capital, ability to develop, acquire and market products successfully, ability to obtain governmental approvals and ability to serve the particular needs of customers. We intend to compete on the basis of safety, effectiveness, convenience, manufacturing superiority, intellectual property, and where appropriate, price.

Because of the broad manifestation of inflammation in chronic disease, numerous pharmaceutical and biotechnology companies are developing or producing anti-inflammatory therapeutic agents. These companies include, but are not limited to: AbbVie, Amgen, Astellas, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Eisai, Eli Lilly, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck, MT Pharma, Nestle/PamLab, Novartis, Pfizer, Reata, Roche/Genentech, Sanofi-Aventis, Servier, Takeda, Vivus.

In addition to competing with non-astaxanthin anti-inflammatory drugs, we intend to compete with microalgal astaxanthin consumer health products on the basis of our global-scale manufacturing capability and product purity. Leading manufacturers of microalgal astaxanthin include Cyanotech, which produces the BioAstin brand; Fuji Health Science (parent company: Fuji Chemical), which produces the AstaREAL brand; and Algatechnologies, which produces the AstaPure brand. Many other companies, including Valensa International (parent company: EID Parry), acquire astaxanthin from these or other smaller manufacturers. We believe that large-scale, multi-fold expansion of naturally produced microalgal astaxanthin would require large amounts of land, and fresh water for open pond systems or large amounts of infrastructure and energy for closed systems, and, consequently, a significant if not overwhelming amount of investment capital. Furthermore, microalgal astaxanthin products, which are lipophilic extracts of a commercially cultivated microalgae, typically have relatively low astaxanthin content, with the majority of the product comprised of other lipophilic, non-astaxanthin microalgal compounds. In contrast, we expect our synthetically manufactured astaxanthin products to have very high astaxanthin content, with consistent pharmaceutical-grade purity. Higher relative astaxanthin content should reduce the size/number of capsules or tablets required to achieve equivalent circulating levels of astaxanthin.

We may also face competition from other synthetic astaxanthin consumer health products, although competitors in this space are limited by the substantial cost and technical expertise required to develop large-scale, industrial production of astaxanthin. DSM, which has operated in the synthetic astaxanthin animal feed market for several decades, announced the marketing of DSM Astaxanthin as a consumer health product under the AstaSana brand in 2013 based on its history of use in the food supply as a color additive, the robust non-clinical safety studies that supported the food color additive approval, and additional long term toxicity studies that were submitted to the FDA in 2005. DSM also announced the GRAS self-affirmation of DSM Astaxanthin in 2015.

Our success will also depend in large part on our ability to obtain and maintain international and domestic patent and other legal protections for the proprietary technology that we consider important to our business. We intend to continue to seek appropriate patent protection for our products where applicable by filing patent applications in the United States and other selected countries. We intend for these patent applications to cover, where applicable, claims for composition of matter, uses, processes for preparation and formulations. Our success will also depend on our ability, and the ability of our current and/or future strategic partners to maintain trade secrets related to proprietary production methods for products that we, or our partners, intend to market.

Raw Materials and Components

We plan to utilize strategic partners and/or contract manufacturers for the production of our products and product candidates. The raw materials and supplies required for the production of our products and product candidates may be available, in some instances from one supplier, and in other instances, from multiple suppliers. In those cases where raw materials are only available through one supplier, such supplier may be either a sole source (the only recognized supply source available to us) or a single source (the only approved supply source for us among other sources). We, our strategic partners, and/or our contract manufacturers will adopt appropriate policies to attempt, to the extent feasible, to minimize our raw material supply risks, including maintenance of greater levels of raw materials inventory and implementation of multiple raw materials sourcing strategies, especially for critical raw materials. Although to date we have not experienced any significant delays in obtaining any raw materials from suppliers, we cannot provide assurance that we, our strategic partners, and/or our contract manufacturers, will not face shortages from one or more of them in the future.

Pursuant to the terms of our BASF Agreement, BASF has agreed to manufacture and supply us with preclinical, clinical, and commercial scale amounts of nature-identical synthetic astaxanthin, ASTX-1, on a mutually exclusive basis for pharmaceutical applications. We are therefore dependent upon BASF to provide a supply of ASTX-1 for the research, development, and commercialization of our product candidates. In the event BASF becomes unable to supply ASTX-1 as provided in the BASF Agreement, we would receive a reasonable royalty-bearing, irrevocable, worldwide non-exclusive license to certain intellectual property rights related to the manufacture of ASTX-1; however, we would have to identify and qualify an acceptable alternate manufacturer.

Customers

We currently do not have any customers for our consumer health and pharmaceutical products.

Intellectual Property

We have obtained and are continuing to seek patent protection for compositions of matter, pharmaceutical compositions, and pharmaceutical uses, in certain disease areas, of our various carotenoid analogs and derivatives. Such carotenoids include, but are not limited to, astaxanthin, zeaxanthin, lutein, and/or lycophyll, and esters and other analogs and derivatives of these compounds. More specifically, we seek to protect: (i) the composition of matter of novel carotenoid analogs and derivatives, (ii) pharmaceutical compositions comprising synthetic or natural preparations of novel or natural occurring carotenoid analogs and derivatives, and (iii) the pharmaceutical use of synthetic preparations of novel or naturally occurring carotenoid analogs and derivatives in specific disease areas, including, but not limited to, the treatment of inflammation and related tissue damage, liver disease, and reperfusion injury, as well as the pharmaceutical use of synthetic or natural preparations of novel or natural occurring carotenoid analogs and derivatives for the reduction of platelet aggregation. We intend to enforce and defend our intellectual property rights consistent with our strategic business objectives.

We own 21 issued patents, including 14 in the United States and 7 others in China, India, Japan, and Hong Kong, related to the technology described above. These patents will expire during the years of 2023 to 2028, subject to any patent term extensions of the individual patent. We have 5 foreign patent applications pending in Europe, Canada, and Brazil, also related to the technology described above. Of these patents and patent applications, 20 patents and 4 patent applications have coverage related to astaxanthin analogs and derivatives; however, our proprietary technologies and business opportunities are not dependent on any single patent or sub-set of patents—the portfolio, which includes coverage related to compositions of matter, pharmaceutical compositions, and pharmaceutical uses, as described above, provides the comprehensive coverage that we deem material to our business.

Our strategic alliances also provide robust intellectual property benefits. BASF owns all manufacturing technology related to astaxanthin developed under the BASF Agreement; however, BASF must exclusively supply astaxanthin to Cardax for pharmaceutical applications, and in the event BASF becomes unable to supply astaxanthin, we would receive a reasonable royalty-bearing, irrevocable, worldwide non-exclusive license to certain intellectual property rights related to the manufacture of astaxanthin.

In February 2012, we licensed our rights to certain monoclonal antibodies against placlitaxel and tangible property relating to assay kits to detect various anti-cancer compounds, including manufacturing and technical know-how, to Biomiga Diagnostics Co. This technology was acquired by us from HBI in 2006 and is unrelated to our primary anti-inflammatory programs. We expect that there will not be any material revenues or benefits under this license.

Employees

On March 28, 2016, we furloughed all of our employees and independent contractors indefinitely and arranged with our Chief Executive Officer, David G. Watumull; our Chief Financial Officer, John B. Russell; and our Vice President, Operations, David M. Watumull, to continue their services for cash compensation equal to the minimum wage. We continue to assess our commercial opportunities, which may include licensing our intellectual property or developing products with others, and may re-engage furloughed employees and contractors from time to time to the extent their services are required at cash compensation equal to the hourly minimum wage. None of our employees are subject to a collective bargaining agreement.

ITEM 1A. RISK FACTORS.

An investment in our common stock, any warrants to purchase our common stock, or any other security that may be issued by us involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this annual report, before making an investment decision. If any of the following risks actually occur, our business, financial condition or results of operations could suffer. In that case, the trading price of our shares of common stock could decline, and you may lose all or part of your investment. You should read the section entitled "Forward-Looking Statements" above for a discussion of what types of statements are forward-looking statements, as well as the significance of such statements in the context of this annual report.

Risks Related to Our Business, Industry and Financial Condition

We have a history of operating losses and have received a going concern opinion from our auditors.

We have incurred substantial net losses since our inception and may continue to incur losses for the foreseeable future, as we continue our product development activities. As a result of our limited operating history, we have limited historical financial data that can be used in evaluating our business and our prospects and in projecting our future operating results. Through December 31, 2015, we have accumulated a total deficit of \$54,150,157.

Additionally, we have received a "going concern" opinion from our independent registered public accounting firm. As reflected in the consolidated financial statements that are filed with this Annual Report on Form 10-K, we are a pre-revenue company with no material amount of earned revenue since our inception. This raises substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise additional capital and implement our business plan. If we are unable to achieve or sustain profitability or to secure additional financing on acceptable terms, we may not be able to meet our obligations as they come due, raising substantial doubts as to our ability to continue as a going concern. Any such inability to continue as a going concern may result in our common stock holders losing their entire investment. There is no guarantee that we will become profitable or secure additional financing on acceptable terms. Our consolidated financial statements contemplate that we will continue as a going concern and do not contain any adjustments that might result if we were unable to continue as a going concern. Changes in our operating plans, our existing and anticipated working capital needs, the acceleration or modification of our expansion plans, increased expenses, potential acquisitions or other events will all affect our ability to continue as a going concern.

We are dependent upon the success of our lead astaxanthin technologies, which may not be successfully commercialized.

We have no commercial products and currently generate no revenue from commercial sales or collaborations and may never be able to develop marketable products. While the FDA does not require clinical trials for consumer health products such as dietary ingredients/supplements and food additives, we plan to conduct clinical trials to demonstrate the safety and efficacy of our product(s) in humans. A failure of any clinical trial can occur at any stage of testing. The results of initial clinical testing of this product may not necessarily indicate the results that will be obtained from later or more extensive testing. Additionally, any observations made with respect to blinded clinical data are inherently uncertain as we cannot know which set of data come from patients treated with an active drug versus the placebo vehicle. Investors are cautioned not to rely on observations coming from blinded data and not to rely on initial clinical trial results as necessarily indicative of results that will be obtained in subsequent clinical trials.

Additionally, our products will be subject to a variety of FDA and other food and drug regulatory regimes. The extent of regulations applicable to our products, and the designations our products may receive from regulatory agencies such as the FDA, are dependent upon the nature and development of our future products and how such products are ultimately commercialized and marketed.

A number of different factors could prevent us from conducting a clinical trial or commercializing our product candidates on a timely basis, or at all.

We, the FDA, other applicable regulatory authorities or an institutional review board, or IRB, may suspend clinical trials of a product candidate at any time for various reasons, including if we or they believe the subjects or patients participating in such trials are being exposed to unacceptable health risks. Among other reasons, adverse side effects of a product candidate on subjects or patients in a clinical trial could result in the FDA or other regulatory authorities suspending or terminating the trial and refusing to approve a particular product candidate for any or all indications of use.

Clinical trials of a product require the enrollment of a sufficient number of patients, including patients who are suffering from the disease or condition the product candidate is intended to treat and who meet other eligibility criteria. Rates of patient enrollment are affected by many factors, and delays in patient enrollment can result in increased costs and longer development times.

Clinical trials also require the review and oversight of IRBs, which approve and continually review clinical investigations and protect the rights and welfare of human subjects. An inability or delay in obtaining IRB approval could prevent or delay the initiation and completion of clinical trials, and the FDA may decide not to consider any data or information derived from a clinical investigation not subject to initial and continuing IRB review and approval.

Numerous factors could affect the timing, cost or outcome of our drug development efforts, including the following:

- delays in filing or acceptance of investigational drug applications for our product candidates;
- difficulty in securing centers to conduct clinical trials;
- conditions imposed on us by the FDA or comparable foreign authorities that are applicable to our business regarding the scope or design of our clinical trials;
- problems in engaging IRBs to oversee trials or problems in obtaining or maintaining IRB approval of studies;
- difficulty in enrolling patients in conformity with required protocols or projected timelines;
- third-party contractors failing to comply with regulatory requirements or to meet their contractual obligations to us in a timely manner;
- our product candidates having unexpected and different chemical and pharmacological properties in humans than in laboratory testing and interacting with human biological systems in unforeseen, ineffective or harmful ways;
- the need to suspend or terminate clinical trials if the participants are being exposed to unacceptable health risks;
- insufficient or inadequate supply or quality of our product candidates or other materials necessary to conduct our clinical trials;
- effects of our product candidates not being the desired effects or including undesirable side effects or the product candidates having other unexpected characteristics;
- the cost of our clinical trials being greater than we anticipate;
- negative or inconclusive results from our clinical trials or the clinical trials of others for similar product candidates or inability to generate statistically significant data confirming the efficacy of the product being tested;
- changes in the FDA's requirements for testing during the course of that testing;
- reallocation of our limited financial and other resources to other programs; and
- adverse results obtained by other companies developing similar products.

It is possible that none of the product candidates that we may develop will obtain the appropriate regulatory approvals necessary to begin selling them or that any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. The time required to obtain FDA and other approvals is unpredictable, but often can take years following the commencement of clinical trials, depending upon the complexity of the product candidate. Any analysis we perform of data from clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenue from the particular product candidate.

We also must comply with clinical trial and post-approval safety and adverse event reporting requirements. Adverse events related to our products must be reported to the FDA in accordance with regulatory timelines based on their severity and expectedness. Failure to make timely safety reports and to establish and maintain related records could result in withdrawal of marketing authorization.

We may also become subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with the FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Approval by the FDA does not assure approval by regulatory authorities outside of the United States.

We have limited experience in managing communications with regulatory agencies, including filing investigational new drug applications, filing new drug applications, submission of promotional materials and generally directing the regulatory processes in all territories.

We may be responsible for managing communications with regulatory agencies, including filing investigational new drug applications, filing new drug applications, submission of promotional materials and generally directing the regulatory processes in all territories. We have limited experience directing such activities and may not be successful with our planned development strategies, on the planned timelines, or at all. Even if any of our product candidates are designated for “fast track” or “priority review” status or if we seek approval under accelerated approval (Subpart H) regulations, such designation or approval pathway does not necessarily mean a faster development process or regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Accelerated development and approval procedures will only be available if the indications for which we are developing products remain unmet medical needs and if our clinical trial results support use of surrogate endpoints, respectively. Even if these accelerated development or approval mechanisms are available to us, depending on the results of clinical trials, we may elect to follow the more traditional approval processes for strategic and marketing reasons, since drugs approved under accelerated approval procedures are more likely to be subjected to post-approval requirements for clinical studies to provide confirmatory evidence that the drugs are safe and effective. If we fail to conduct any such required post-approval studies or if the studies fail to verify that any of our product candidates are safe and effective, our FDA approval could be revoked. It can be difficult, time-consuming and expensive to enroll patients in such clinical trials because physicians and patients are less likely to participate in a clinical trial to receive a drug that is already commercially available. Drugs approved under accelerated approval procedures also require regulatory pre-approval of promotional materials that may delay or otherwise hinder commercialization efforts.

We intend to operate in highly competitive industries, and our failure to compete effectively could adversely affect our market share, financial condition and growth prospects. If competitors are better able to develop and market products that are more effective, or gain greater acceptance in the marketplace than our products, our commercial opportunities may be reduced or eliminated.

The consumer health and pharmaceutical industries are constantly evolving, and scientific advances are expected to continue at a rapid pace. This results in intense competition among companies operating in the industry. Other, larger companies may have, or may be developing, products that compete with our products and may significantly limit the market acceptance of our products or render them obsolete. Our technical and/or business competitors would include major pharmaceutical companies, biotechnology companies, consumer health companies, universities and nonprofit research institutions and foundations. Most of these competitors have significantly greater research and development capabilities than we have, as well as substantial marketing, financial and managerial resources. Our lead product is expected to primarily compete against consumer health and pharmaceutical products that provide anti-inflammatory benefits. In addition, there are several other companies, both public and private, that service the same markets as we do, all of which compete to some degree with us.

The primary competitive factors facing us include safety, efficacy, price, quality, breadth of product line, manufacturing quality and capacity, service, marketing and distribution capabilities. Our current and future competitors may have greater resources, more widely accepted and innovative products and stronger name recognition than we do. Our ability to compete is affected by our ability, or that of our strategic partners, to:

- develop or acquire new products and innovative technologies;
- obtain regulatory clearance and compliance for our products;
- manufacture and sell our products cost-effectively;
- meet all relevant quality standards for our products in their particular markets;
- respond to competitive pressures specific to each of our geographic and product markets;
- protect the proprietary technology of our products and avoid infringement of the proprietary rights of others;
- market our products;
- attract and retain skilled employees, including sales representatives;
- maintain and establish distribution relationships; and
- engage in acquisitions, joint ventures or other collaborations.

Competitors could develop products that are more effective, achieve favorable reimbursement status from third-party payors, cost less or are ready for commercial introduction before our products. If our competitors are better able to develop and patent products earlier than we can, or develop more effective and/or less expensive products that render our products obsolete or non-competitive, our business will be harmed and our commercial opportunities will be reduced or eliminated.

We believe that the market in which we compete in is also highly sensitive to the introduction of new products, including various prescription drugs, which may rapidly capture a significant share of the market. In the United States, we expect to also compete for sales with heavily advertised national brands manufactured by large pharmaceutical, biotechnology, and consumer health companies, as well as other retailers.



As some products gain market acceptance, we may experience increased competition for those products as more participants enter the market. Currently, we are not a manufacturer. To the extent that we engage third-party manufacturers or use strategic alliances to produce our products, our manufacturing capabilities may not be adequate or sufficient to compete with large scale, direct or third-party manufacturers. Certain of our potential competitors are larger than us and have longer operating histories, customer bases, greater brand recognition and greater resources for marketing, advertising and product promotion. They may be able to secure inventory from vendors on more favorable terms, operate with a lower cost structure or adopt more aggressive pricing policies. In addition, our potential competitors may be more effective and efficient in introducing new products. We may not be able to compete effectively, and our attempt to do so may require us to increase marketing and/or reduce our prices, which may result in lower margins. Failure to effectively compete could adversely affect our market share, financial condition and growth prospects.

Market acceptance of our proposed products is vital to our future success.

The commercial success of our proposed products is dependent upon the acceptance of such products. Our proposed products may not gain and maintain any significant degree of market acceptance among potential users, healthcare providers, or acceptance by third-party payors, such as health insurance companies. The medical indications that can be treated by our proposed products can also be treated by other products or techniques. The medical community widely accepts alternative treatments, and certain of these other treatments have a long history of use. We cannot be certain that our proposed products and the procedures in which they are used will be able to replace those established treatments or that users will accept and utilize our products or any other medical products that we may market.

Market acceptance will depend upon numerous factors, many of which are not under our control, including:

- the safety and efficacy of our products;
- favorable regulatory approval and product labeling;
- the availability, safety, efficacy and ease of use of alternative products or treatments;
- our ability to educate potential users on the advantages of our products;
- the price of our products relative to alternative technologies; and
- the availability of third-party reimbursement.

If our proposed products do not achieve significant market acceptance, our future revenues and profitability would be adversely affected.

The pharmaceutical and consumer health industries are subject to extensive and complex healthcare regulation. Any determination that we have violated federal or state laws applicable to us that regulate healthcare would have a material adverse effect on our business, prospects and financial condition.

Federal and state laws regulating healthcare are extensive and complex. The laws applicable to our business are subject to evolving interpretations, and therefore we cannot be sure that a review of our operations by federal or state courts or regulatory authorities will not result in a determination that we have violated one or more provisions of federal or state law. Any such determination could have a material adverse effect on our business, prospects and financial condition.

If we fail to comply with FDA regulations our business could suffer.

The manufacture and marketing of pharmaceutical and consumer health products are subject to extensive regulation by the FDA and foreign and state regulatory authorities. In the United States, pharmaceutical and consumer health companies such as ours must comply with laws and regulations promulgated by the FDA. These laws and regulations require various authorizations prior to a product being marketed in the United States. Manufacturing facilities and practices are also subject to FDA regulations. The FDA regulates the clinical testing, manufacture, labeling, sale, distribution and promotion of pharmaceutical and consumer health products in the United States. Our failure to comply with regulatory requirements, including any future changes to such requirements, could have a material adverse effect on our business, prospects, financial condition and results of operations.

Even after clearance or approval of a product, we are subject to continuing regulation by the FDA, including the requirements of registering our facilities and listing our products with the FDA. We are subject to reporting regulations. These regulations require us to report to the FDA if any of our products may have caused or contributed to a death or serious injury and such product or a similar product that we market would likely cause or contribute to a death or serious injury. Unless an exemption applies, we must report corrections and removals to the FDA where the correction or removal was initiated to reduce a risk to health posed by the product or to remedy a violation of the Food, Drug and Cosmetic Act. The FDA also requires that we maintain records of corrections or removals, regardless of whether such corrections and removals are required to be reported to the FDA. In addition, the FDA closely regulates promotion and advertising, and our promotional and advertising activities could come under scrutiny by the FDA.

The FDA also requires that manufacturing be in compliance with its Quality System Regulation, or QSR. The QSR covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. Our failure to maintain compliance with the QSR requirements could result in the shutdown of, or restrictions on, our manufacturing operations, to the extent we have any, and the recall or seizure of our products, which would have a material adverse effect on our business. In the event that one of our suppliers fails to maintain compliance with our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result.

The FDA has broad enforcement powers. If we violate applicable regulatory requirements, the FDA may bring enforcement actions against us, which could have a material adverse effect on our business, prospects, financial condition and results of operations. Violations of regulatory requirements, at any stage, including after approval, may result in various adverse consequences, including the delay by a regulatory agency in approving or refusal to approve a product, withdrawal or recall of an approved product from the market, other voluntary agency-initiated action that could delay further development or marketing, as well as the imposition of criminal penalties against the manufacturer and NDA holder.

The extent of FDA regulations applicable to us, and whether our products are ultimately designated as drugs (including active pharmaceutical ingredients) or dietary supplements (including dietary ingredients), will depend upon how our products are ultimately commercialized. Because we are currently evaluating the extent of our pharmaceutical program, we are unable to determine the extent of FDA regulations applicable to our product candidates. Furthermore, our products may be commercialized by us or by other parties through licensing arrangements, joint ventures, or other alliances, and our burden of complying with any regulations applicable to our product candidates will depend upon the nature and extent of any relationships with such partners. While consumer health products are not as extensively regulated as pharmaceutical products, the extent of any other regulatory regimes to which we may be subject will depend upon the specific products we ultimately produce.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly by establishing Medicare Part D and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs under Medicare Part B. In addition, this legislation provided authority for limiting the number of drugs that Medicare will cover in any therapeutic class under the new Medicare Part D program. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the Affordable Care Act, a law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs, effective the first quarter of 2010, and revising the definition of "average manufacturer price," or AMP, for reporting purposes, which could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization, and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. The Centers for Medicare and Medicaid Services, which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid drug rebates to the utilization that occurs in the United States territories, such as Puerto Rico and the Virgin Islands. Also effective in 2010, the Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing, although, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase. Furthermore, as of 2011, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products and requires manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners. Notably, a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the full effect of the Affordable Care Act, the new law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

The Affordable Care Act and other regulations regarding the United States healthcare system are subject to substantial reformation. For example, some members of the United States Congress have proposed delaying the implementation of the Affordable Care Act or the repeal of this legislation. The legislation has not been repealed. In addition, President Obama has, and may continue, to modify the Affordable Care Act through executive orders and we cannot provide any assurance of the effect of any such modifications. We are not able to provide any assurance that the continued healthcare reform debate will not result in legislation, regulation or executive action by the President of the United States that is adverse to our business.

We rely on third-parties to supply and manufacture our proposed products. If these third-parties do not perform as expected or if our agreements with them are terminated, our business, prospects, financial condition and results of operations would be materially adversely affected.

We outsource our manufacturing to third-parties such as BASF. Our reliance on contract manufacturers and suppliers exposes us to risks, including the following:

- We rely on our suppliers and manufacturers to provide us with the needed products or components in a timely fashion and of an acceptable quality. An uncorrected defect or supplier's variation in a component could harm our or our third-party manufacturers' ability to manufacture, and our ability to sell, products and may subject us to product liability claims.
- The facilities of our third-party manufacturers must satisfy production and quality standards set by applicable regulatory authorities. Regulatory authorities periodically inspect manufacturing facilities to determine compliance with these standards. If we or our third-party manufacturers fail to satisfy these requirements, the facilities could be shut down.
- These manufacturing operations could also be disrupted or delayed by fire, earthquake or other natural disaster, a work stoppage or other labor-related disruption, failure in supply or other logistical channels, electrical outages or other reasons. If there was any such disruption to any of these manufacturing facilities, our third-party manufacturers would potentially be unable to manufacture our products.
- A third-party manufacturer or supplier could decide to terminate our manufacturing or supply arrangement, including due to a disagreement between us and such third-party manufacturer, if the third-party manufacturer determines not to further manufacture our products, or if we fail to comply with our obligations under such arrangements.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

We currently rely on a limited number of suppliers to provide key components for our products. If these or other suppliers become unable to provide components in the volumes needed or at an acceptable price or quality, we would have to identify and qualify acceptable replacements from alternative suppliers. We may experience stoppages in the future. We may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to produce and supply our products could be impaired.

To the extent we are able to identify alternative suppliers, qualifying suppliers is a lengthy process. There are a limited number of manufacturers and suppliers that may satisfy applicable requirements. In addition, FDA regulations may require additional testing of any components from new suppliers prior to our use of these materials or components, which testing could delay or prevent the supply of components. Moreover, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products, which could take a significant period of time.

Each of these risks could delay the development or commercialization of our products or result in higher costs or deprive us of potential product revenues. Furthermore, delays or interruptions in the manufacturing process could limit or curtail our ability to meet demand for our products and/or make commercial sales, unless and until the manufacturing capability at the facilities are restored and re-qualified or alternative manufacturing facilities are developed or brought on-line and “scaled up.” Any such delay or interruption could have a material adverse effect on our business, prospects, financial condition and results of operations.

An unexpected interruption or shortage in the supply or significant increase in the cost of components could limit our ability to manufacture any products, which could reduce our sales and margins.

To the extent we engage in relationships with contract manufacturers in the future, an unexpected interruption of supply or a significant increase in the cost of components, whether to us or to our contract manufacturers for any reason, such as regulatory requirements, import restrictions, loss of certifications, disruption of distribution channels as a result of weather, terrorism or acts of war, or other events, could result in significant cost increases and/or shortages of our products. Our inability to obtain a sufficient amount of products or to pass through higher cost of products we offer could have a material adverse effect on our business, financial condition or results of operations.

We have limited experience in marketing our products and services.

We have undertaken limited marketing efforts for our proposed products and services. Our sales and marketing teams, and/or those of our strategic partners, will compete against the experienced and well-funded sales organizations of competitors. Our future revenues and ability to achieve profitability will depend largely on the effectiveness of our sales and marketing team, and we will face significant challenges and risks related to marketing our services, including, but not limited to, the following:

- the ability of sales representatives to obtain access to or persuade adequate numbers of healthcare providers to purchase and use our products and services;
- the ability to recruit, properly motivate, retain, and train adequate numbers of qualified sales and marketing personnel;
- the costs associated with hiring, training, maintaining, and expanding an effective sales and marketing team; and
- assuring compliance with government regulatory requirements affecting the healthcare industry in general and our products in particular.

Although we will be relying primarily on strategic partners to distribute our products, we may seek to establish a network of distributors in selected markets to market, sell and distribute our products. If we fail to select or use appropriate distributors, or if the sales and marketing strategies of such distributors prove ineffective in generating sales of our products, our future revenues would be adversely affected and we might never become profitable.

We plan to rely on third-party distributors for sales, marketing and distribution activities.

We plan to rely on third-party distributors to sell, market, and distribute our products. Because we intend to rely on third-party distributors for sales, marketing and distribution activities, we will be subject to a number of risks associated with our dependence on these third-party distributors, including:

- lack of day-to-day control over the activities of third-party distributors;
- third-party distributors may not fulfill their obligations to us or otherwise meet our expectations;
- third-party distributors may terminate their arrangements with us on limited or no notice or may change the terms of these arrangements in a manner unfavorable to us for reasons outside of our control; and
- disagreements with our distributors could require or result in costly and time-consuming litigation or arbitration.

If we fail to establish and maintain satisfactory relationships with third-party distributors, we may be unable to sell, market and distribute our products, our future revenues and market share may not grow as anticipated, and we could be subject to unexpected costs which would harm our results of operations and financial condition.

Commercialization of our proposed products and services will require us to build and maintain sophisticated sales and marketing teams.

We have limited prior experience with commercializing our products. To successfully commercialize our products and services, we will need to establish and maintain sophisticated sales and marketing teams. While we intend to use current Company employees to lead our marketing efforts, we may choose to expand our marketing and sales team. Experienced sales representatives may be difficult to locate and retain, and all new sales representatives will need to undergo extensive training. There is no assurance that we will be able to recruit and retain sufficiently skilled sales representatives, or that any new sales representatives will ultimately become productive. If we are unable to recruit and retain qualified and productive sales personnel, our ability to commercialize our products and to generate revenues will be impaired, and our business will be harmed.

We may not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, contract research organizations, contract manufacturing organizations, clinical research organizations and other third-parties to support our discovery efforts, to formulate product candidates, to manufacture our product candidates and to conduct clinical trials for some or all of our product candidates. We cannot guarantee that we will be able to successfully negotiate agreements for or maintain relationships with collaborators, partners, licensees, contractors, clinical investigators, vendors and other third-parties on favorable terms, if at all. Our ability to successfully negotiate such agreements will depend on, among other things, potential partners' evaluation of the superiority of our technology over competing technologies, the quality of the preclinical and clinical data that we have generated and the perceived risks specific to developing our product candidates. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates. We cannot necessarily control the amount or timing of resources that our contract partners will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion. We may not be able to readily terminate any such agreements with contract partners even if such contract partners do not fulfill their obligations to us.

We currently rely on our strategic partnership with BASF for a significant part of our future revenue. We are dependent upon BASF performing their obligations under our current arrangements with them. If BASF becomes unable to provide its services as provided in such arrangements, we would have to identify and qualify an acceptable replacement. We may experience stoppages in the future. We may not be able to find a sufficient alternative provider in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to produce and supply our products could be impaired.

We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability.

We expend substantial funds to develop our proprietary technologies, and additional substantial funds will be required for further research and development, including preclinical testing and clinical trials of any product candidates, and to manufacture and market any products that are approved for commercial sale. Because the successful development of our products is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate enough revenue, even if we are able to commercialize any of our product candidates, to become profitable.

We may be subject to product liability claims. Our insurance may not be sufficient to cover these claims, or we may be required to recall our products.

Our business is to develop and commercialize, among other things, pharmaceutical and consumer health products that provide anti-inflammatory benefits. As a result, we will face an inherent risk of product liability claims. The pharmaceutical industry has been historically litigious. Since our products are to be used in the human body, manufacturing errors, design defects or packaging defects could result in injury or death to the patient. This could result in a recall of one or more of our products and substantial monetary damages. Any product liability claim brought against us, with or without merit, could result in a diversion of our resources, an increase in our product liability insurance premiums and/or an inability to secure coverage in the future. We may also have to pay any amount awarded by a court in excess of our policy limits. In addition, any recall of our products, whether initiated by us or by a regulatory agency, may result in adverse publicity for us that could have a material adverse effect on our business, prospects, financial condition and results of operations. Our product liability insurance policies will have various exclusions; therefore, we may be subject to a product liability claim or recall for which we have no insurance coverage. In such a case, we may have to pay the entire amount of the award or costs of the recall. Finally, product liability insurance may be expensive and may not be available in the future on acceptable terms, or at all.

If we experience product recalls, we may incur significant and unexpected costs and damage to our reputation and, therefore, could have a material adverse effect on our business, financial condition or results of operations.

We may be subject to product recalls, withdrawals or seizures if any of our products are believed to cause injury or illness or if we are alleged to have violated governmental regulations in the manufacture, labeling, promotion, sale or distribution of our products. A recall, withdrawal or seizure of any of our products could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our products. In addition, a recall, withdrawal or seizure of any of our products would require significant management attention, would likely result in substantial and unexpected expenditures and could materially and adversely affect our business, financial condition or results of operations.

If we are unable to obtain and maintain protection of our intellectual property, the value of our products may be adversely affected.

Our business is dependent in part upon our ability to use intellectual property rights to protect our products from competition. To protect our products, we rely on a combination of patent and other intellectual property laws, employment, confidentiality and invention assignment agreements with our employees and contractors, and confidentiality agreements and protective contractual provisions with our partners, licensors and other third-parties. These methods, however, afford us only limited protection against competition from other products.

We attempt to protect our intellectual property position, in part, by filing patent applications related to our proprietary technology, inventions and improvements that are important to our business. However, our patent position is not likely by itself to prevent others from commercializing products that compete directly with our products. Moreover, we do not have patent protection for certain components of our products and our patent applications can be challenged. In addition, we may fail to receive any patent for which we have applied, and any patent owned by us or issued to us could be challenged, invalidated, or held to be unenforceable. We also note that any patent granted may not provide a competitive advantage to us. Our competitors may independently develop technologies that are substantially similar or superior to our technologies. Further, third-parties may design around our patented or proprietary products and technologies.

We rely on certain trade secrets and we may not be able to adequately protect our trade secrets even with contracts with our personnel and third-parties. Also, any third-party could independently develop and have the right to use, our trade secret, know-how and other proprietary information. If we are unable to protect our intellectual property rights, our business, prospects, financial condition and results of operations could suffer materially.

Our ability to market our products may be impaired by the intellectual property rights of third-parties.

Our success depends in part on our products not infringing on the patents and proprietary rights of other parties. For instance, in the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not published until the patent issues. As a result, there may be patents and patent applications of which we are unaware, and avoiding patent infringement may be difficult.

Our industry is characterized by a large number of patents, patent applications and frequent litigation based on allegations of patent infringement. Competitors may own patents or proprietary rights, or have filed patent applications, related to products that are similar to ours. We may not be aware of all of the patents and pending applications potentially adverse to our interests that may have been issued to others. Moreover, since there may be unpublished patent applications that could result in patents with claims relating to our products, we cannot be sure that our current products will not infringe any patents that might be issued or filed in the future. Based on the litigious nature of our industry and the fact that we may pose a competitive threat to some companies who own or control various patents, we believe it is possible that one or more third-parties may assert a patent infringement claim seeking damages or enjoining us from the manufacture or marketing of one or more of our products. Such a lawsuit may have already been filed against us without our knowledge, or may be filed in the near future. If any future claim of infringement against us was successful, we may be required to pay substantial damages, cease the infringing activity or obtain the requisite licenses or rights to use the technology, which may not be available to us on acceptable terms, if at all. Even if we were able to obtain rights to a third-party's intellectual property rights, these rights may be non-exclusive, thereby giving our competitors potential access to the same rights and weakening our market position. Moreover, regardless of the outcome, patent litigation could significantly disrupt our business, divert our management's attention and consume our financial resources. We cannot predict if or when any third-party patent holder will file suit for patent infringement.

We may be involved in lawsuits or proceedings to protect or enforce our intellectual property rights or to defend against infringement claims, which could be expensive and time consuming.

Litigation may be necessary to enforce our intellectual property rights, protect our trade secrets or determine the validity and scope of the proprietary rights of others. Interference proceedings conducted by a patent and trademark office may be necessary to determine the priority of inventions with respect to our patent applications. Litigation or interference proceedings could result in substantial costs and diversion of resources and management attention. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. In addition, we may be enjoined from marketing one or more of our products if a court finds that such products infringe the intellectual property rights of a third-party.

During litigation, we may not be able to prevent the confidentiality of certain of our proprietary rights because of the substantial amount of discovery required in connection with intellectual property litigation. In addition, during the course of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors or customers perceive these results to be negative, it could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our insurance liability coverage is limited and may not be adequate to cover potential losses.

In the ordinary course of business, we purchase insurance coverage (e.g., liability coverage) to protect us against claims made by third parties and employees for property damage or personal injuries. However, the protection provided by such insurance is limited in significant respects and, in some instances, we have no coverage and certain of our insurance policies have substantial “deductibles” or have limits on the maximum amounts that may be recovered. Insurers have also introduced new exclusions or limitations of coverage for claims related to certain perils including, but not limited to, mold and terrorism. If a series of losses occurred, such as from a series of lawsuits in the ordinary course of business each of which were subject to the deductible amount, or if the maximum limit of the available insurance was substantially exceeded, we could incur losses in amounts that would have a material adverse effect on our results of operations and financial condition. We do not presently have any product liability insurance that would provide coverage for any allegation of product defects or related claims. We will review our ability to obtain such insurance coverage later, but there cannot be any assurance that such insurance coverage will be available on acceptable terms.

Our operating results may fluctuate, which may result in volatility of our share price.

Our operating results, including components of operating results, can be expected to fluctuate from time to time in the future. Some of the factors that may cause these fluctuations include:

- the impact of acquisitions;
- market acceptance of our existing products, as well as products in development;
- the timing of regulatory approvals;
- our ability or the ability of third-party distributors to sell, market, and distribute our products;
- our ability or the ability of our contract manufacturers to manufacture our products efficiently; and
- the timing of our research and development expenditures.

If we are unable to manage our expected growth, our future revenue and operating results may be adversely affected.

Our anticipated growth is expected to place a significant strain on our management, operational and financial resources. Our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth. To manage our growth we will be required to improve existing, and implement new, operational and financial systems, procedures and controls and expand, train and manage our growing employee base. We expect that we may need to increase our management personnel to oversee our expanding operations. Recruiting and retaining qualified individuals can be difficult. If we are unable to manage our growth effectively, or are unsuccessful in recruiting qualified management personnel, our business, prospects, financial condition and results of operations could be harmed.

We are highly dependent on our senior management, and if we are not able to retain them or to recruit and retain additional qualified personnel, our business will suffer.

We are highly dependent upon our senior management, including David G. Watumull, our President and Chief Executive Officer, Gilbert M. Rishon, our Chief Science Officer, Timothy J. King, our Vice President, Research, John B. Russell, our Chief Financial Officer, David M. Watumull, our Vice President, Operations, and Nicholas Mitsakos, our Executive Chairman. The loss of services of David G. Watumull or any other member of our senior management could have a material adverse effect on our business, prospects, financial condition and results of operations. We carry a \$1 million “key person” life insurance policy on David G. Watumull but do not carry similar insurance for any of our other senior executives.

We may choose to increase our management personnel. For example, we will need to obtain certain additional functional capability, including regulatory, sales, quality assurance and control, either by hiring additional personnel or by outsourcing these functions to qualified third-parties. We may not be able to engage these third-parties on terms favorable to us. Also, we may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel among companies that operate in our markets. The trend in the pharmaceutical industry of requiring sales and other personnel to enter into non-competition agreements prior to starting employment exacerbates this problem, since personnel who have made such a commitment to their current employers are more difficult to recruit. If we fail to identify, attract, retain and motivate these highly skilled personnel, or if we lose current employees, our business, prospects, financial conditions and results of operations could be adversely affected.

Our ability to grow and compete in the future will be adversely affected if adequate capital is not available to us or not available on terms favorable to us.

The ability of our business to grow and compete depends on the availability of adequate capital, which in turn depends in large part on our cash flow from operations and the availability of equity and debt financing. We cannot assure you that our cash flow from operations will be sufficient or that we will be able to obtain equity or debt financing on acceptable terms or at all to implement our growth strategy. As a result, we cannot assure you that adequate capital will be available to finance our current growth plans, take advantage of business opportunities or respond to competitive pressures, any of which could harm our business. Additionally, if adequate additional financing is not available on acceptable terms, we may not be able to continue our business operations. Any additional capital, investment or financing of our business may result in dilution of our stockholders or be on terms and conditions that impair our ability to profitably conduct our business.

You may have limited access to information regarding our Company because we are a limited reporting company exempt from many regulatory requirements.

As a filer subject to Section 15(d) of the Exchange Act, the Company is not required to prepare proxy or information statements; our common stock is not subject to the protection of the going private regulations; the Company is subject to only limited portions of the tender offer rules; our officers, directors, and more than ten (10%) percent stockholders are not required to file beneficial ownership reports about their holdings in our Company; such persons are not subject to the short-swing profit recovery provisions of the Exchange Act; and stockholders of more than five percent (5%) are not required to report information about their ownership positions in the securities. As a result, investors will have reduced visibility as to the Company and its financial condition.

Risks Related to Ownership of Our Common Stock

Our common stock has a limited trading market, which could affect your ability to sell shares of our common stock and the price you may receive for our common stock.

Our common stock is currently traded in the over-the-counter market and “bid” and “asked” quotations regularly appear on the OTCQB maintained by OTC Markets, Inc. under the symbol “CDXI”. There is only limited trading activity in our securities. We have a relatively small public float compared to the number of our shares outstanding. Accordingly, we cannot predict the extent to which investors’ interest in our common stock will provide an active and liquid trading market, which could depress the trading price of our common stock and could have a long-term adverse impact on our ability to raise capital in the future. Due to our limited public float, we may be vulnerable to investors taking a “short position” in our common stock, which would likely have a depressing effect on the price of our common stock and add increased volatility to our trading market. The volatility of the market for our common stock could have a material adverse effect on our business, results of operations and financial condition. There cannot be any guarantee that an active trading market for our securities will develop or, if such a market does develop, will be sustained. Accordingly, investors must be able to bear the financial risk of losing their entire investment in our common stock.

We may voluntarily file for deregistration of our common stock with the Commission.

Compliance with the periodic reporting requirements required by the Securities and Exchange Commission (the “Commission” or “SEC”) consumes a considerable amount of both internal, as well external, resources and represents a significant cost for us. Our senior management team has relatively limited experience managing a company subject to the reporting requirements of the Exchange Act, and the regulations promulgated thereunder. Our management will be required to design and implement appropriate programs and policies in responding to increased legal, regulatory compliance and reporting requirements, and any failure to do so could lead to the imposition of fines and penalties and harm our business. In addition, if we are unable to continue to devote adequate funding and the resources needed to maintain such compliance, while continuing our operations, we may be in non-compliance with applicable SEC rules or the securities laws, and be delisted from the OTCQB or other market we may be listed on, which would result in a decrease in or absence of liquidity in our common stock, and potentially subject us and our officers and directors to civil, criminal and/or administrative proceedings and cause us to voluntarily file for deregistration of our common stock with the Commission.

Future sales of our common stock in the public market could lower the price of our common stock and impair our ability to raise funds in future securities offerings.

We intend to raise additional capital through the sale of our securities. Future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then prevailing market price of our common stock and could make it more difficult for us to raise funds in the future through the sale of our securities.

We may issue shares of preferred stock that subordinate your rights and dilute your equity interests.

We believe that for us to successfully execute our business strategy we will need to raise investment capital and it may be preferable or necessary to issue preferred stock to investors. Preferred stock may grant the holders certain preferential rights in voting, dividends, liquidation or other rights in preference over a company’s common stock.

The issuance by us of preferred stock could dilute both the equity interests and the earnings per share of existing holders of our common stock. Such dilution may be substantial, depending upon the number of shares issued. The newly authorized shares of preferred stock could also have voting rights superior to our common stock, and in such event, would have a dilutive effect on the voting power of our existing stockholders.

Any issuance of preferred stock with voting rights could, under certain circumstances, have the effect of delaying or preventing a change in control of us by increasing the number of outstanding shares entitled to vote and by increasing the number of votes required to approve a change in control of us. Shares of voting or convertible preferred stock could be issued, or rights to purchase such shares could be issued, to render more difficult or discourage an attempt to obtain control of us by means of a tender offer, proxy contest, merger or otherwise. Such issuances could therefore deprive our stockholders of benefits that could result from such an attempt, such as the realization of a premium over the market price that such an attempt could cause. Moreover, the issuance of such shares of preferred stock to persons friendly to our Board of Directors could make it more difficult to remove incumbent managers and directors from office even if such change were to be favorable to stockholders generally.

The market price of our common stock may be volatile and may be affected by market conditions beyond our control.

The market for our common shares is characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will continue to be more volatile than a seasoned issuer for the indefinite future. The volatility in our share price is attributable to a number of factors. First, our shares of common stock are sporadically and thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline precipitously in the event that a large number of shares of our common stock are sold on the market without commensurate demand, as compared to a seasoned issuer which could better absorb those sales without adverse impact on its share price. Second, we are a speculative or “risky” investment due to our limited operating history and lack of profits to date, and uncertainty of future market acceptance for our potential products. As a consequence of this enhanced risk, more risk-averse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. Many of these factors are beyond our control and may decrease the market price of our common stock, regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our common stock will be at any time, including as to whether our common stock will sustain its current market price, or as to what effect the sale of shares or the availability of common stock for sale at any time will have on the prevailing market price.

The market price of our common stock is subject to significant fluctuations in response to, among other factors:

- changes in our financial performance or a change in financial estimates or recommendations by securities analysts;
- announcements of innovations or new products or services by us or our competitors;
- the emergence of new competitors or success of our existing competitors;
- operating and market price performance of other companies that investors deem comparable;
- changes in our Board of Directors or management;
- sales or purchases of our common stock by insiders;
- commencement of, or involvement in, litigation;
- changes in governmental regulations; and
- general economic conditions and slow or negative growth of related markets.

In addition, if the market for stock in our industry, or the stock market in general, experiences a loss of investor confidence, the market price of our common stock could decline for reasons unrelated to our business, financial condition or results of operations. If any of the foregoing occurs, it could cause the price of our common stock to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and distract our Board of Directors and management.

We do not intend to pay dividends for the foreseeable future, and you must rely on increases in the market prices of our common stock for returns on your investment.

For the foreseeable future, we intend to retain any earnings to finance the development and expansion of our business, and we do not anticipate paying any cash dividends on our common stock. Accordingly, investors must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Investors seeking cash dividends should not purchase our common stock. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant.

We are subject to penny stock regulations and restrictions and you may have difficulty selling shares of our common stock.

The Commission has adopted regulations which generally define so-called “penny stocks” as an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exemptions. Our common stock is a “penny stock”, and we are subject to Rule 15g-9 under the Exchange Act, or the Penny Stock Rule. This rule imposes additional sales practice requirements on broker-dealers that sell such securities to persons other than established customers and “accredited investors” (generally, individuals with a net worth in excess of \$1,000,000 or annual income exceeding \$200,000, or \$300,000 together with their spouses). For transactions covered by Rule 15g-9, a broker-dealer must make a special suitability determination for the purchaser and receive the purchaser’s written consent to the transaction prior to sale. As a result, this rule affects the ability of broker-dealers to sell our securities and affects the ability of purchasers to sell any of our securities in the secondary market.

For any transaction involving a penny stock, unless exempt, the rules require delivery, prior to any transaction in a penny stock, of a disclosure schedule prepared by the Commission relating to the penny stock market. Disclosure is also required to be made about sales commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements are required to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stock.

There can be no assurance that our shares of common stock will qualify for exemption from the Penny Stock Rule. In any event, even if our common stock were exempt from the Penny Stock Rule, we would remain subject to Section 15(b)(6) of the Exchange Act, which gives the Commission the authority to restrict any person from participating in a distribution of penny stock if the Commission finds that such a restriction would be in the public interest.

In addition to the “penny stock” rules described above, the Financial Industry Regulatory Authority (“FINRA”) has adopted similar rules that may also limit a stockholder’s ability to buy and sell our common stock. FINRA rules require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for such customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer’s financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. The FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

We maintain a facility of approximately 738 square feet at 2800 Woodlawn Drive, Honolulu, Hawaii, which is leased on a month-to-month basis. We also maintained a laboratory located in a leased facility of approximately 1,094 square feet at 99-193 Aiea Heights Drive, Aiea, Hawaii, which we vacated in February, 2015. We believe that our facility is adequate for our current purposes.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we may become involved in various lawsuits and legal proceedings that arise in the ordinary course of business. However, litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that we believe will have a material adverse effect on our business, financial condition or operating results.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our shares of common stock are quoted on the OTCQB under the symbol CDXI. Prior to February 21, 2014, shares of our common stock were quoted on the OTCQB under the symbol KOFF, commencing on August 30, 2012. The high and low bid quotations for our shares of common stock for each full quarterly period within the two most recent fiscal years are:

<u>Year Ended December 31, 2014</u>	<u>High</u>	<u>Low</u>
March 31, 2014	\$ 8.00	\$ 0.50
June 30, 2014	\$ 1.45	\$ 0.86
September 30, 2014	\$ 1.00	\$ 0.41
December 31, 2014	\$ 0.64	\$ 0.29
<u>Year Ended December 31, 2015</u>	<u>High</u>	<u>Low</u>
March 31, 2015	\$ 0.44	\$ 0.15
June 30, 2015	\$ 0.32	\$ 0.11
September 30, 2015	\$ 0.77	\$ 0.08
December 31, 2015	\$ 0.95	\$ 0.20
<u>Year Ended December 31, 2016</u>	<u>High</u>	<u>Low</u>
March 31, 2016 (through March 28, 2016)	\$ 0.28	\$ 0.03

Such quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and do not necessarily represent actual transactions.

Holdings

As of March 28, 2016 there were approximately 450 stockholders of record of our common stock. The number of stockholders does not include beneficial owners holding shares through nominee names.

Dividends

We have never paid any cash dividends and intend, for the foreseeable future, to retain any future earnings for the development of our business. Our future dividend policy will be determined by our Board of Directors on the basis of various factors, including our results of operations, financial condition, capital requirements and investment opportunities.

Penny Stock Regulations

The Commission has adopted regulations which generally define so-called "penny stocks" as an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exemptions. Our common stock is a "penny stock", and we are subject to Rule 15g-9 under the Exchange Act, or the Penny Stock Rule. This rule imposes additional sales practice requirements on broker-dealers that sell such securities to persons other than established customers and "accredited investors" (generally, individuals with a net worth in excess of \$1,000,000 or annual income exceeding \$200,000, or \$300,000 together with their spouses). For transactions covered by Rule 15g-9, a broker-dealer must make a special suitability determination for the purchaser and receive the purchaser's written consent to the transaction prior to sale. As a result, this rule affects the ability of broker-dealers to sell our securities and affects the ability of purchasers to sell any of our securities in the secondary market.

For any transaction involving a penny stock, unless exempt, the rules require delivery, prior to any transaction in a penny stock, of a disclosure schedule prepared by the Commission relating to the penny stock market. Disclosure is also required to be made about sales commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements are required to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stock.

There can be no assurance that our shares of common stock will qualify for exemption from the Penny Stock Rule. In any event, even if our common stock were exempt from the Penny Stock Rule, we would remain subject to Section 15(b)(6) of the Exchange Act, which gives the Commission the authority to restrict any person from participating in a distribution of penny stock if the Commission finds that such a restriction would be in the public interest.

In addition to the “penny stock” rules described above, the FINRA has adopted similar rules that may also limit a stockholder’s ability to buy and sell our common stock. FINRA rules require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for such customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer’s financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. The FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit the ability of our stockholders to sell their shares and have an adverse effect on the market for our shares.

Securities Authorized for Issuance under Equity Compensation Plans

We adopted, and our stockholders approved, the Cardax, Inc. 2014 Equity Compensation Plan (the “2014 Plan”), effective as of February 7, 2014. Under such plan, we may grant equity based incentive awards, including options, restricted stock, and other stock-based awards, to any directors, employees, advisers, and consultants that provide services to us or any of our subsidiaries on terms and conditions that are from time to time determined by us. An aggregate of 45,420,148 shares of our common stock are reserved for issuance under the 2014 Plan. Options for the purchase of 34,213,711 shares of our common stock have been granted, options for the purchase of 46,357 shares of our common stock have been exercised, and options for the purchase of 34,167,354 shares of our common stock are outstanding as of March 28, 2016. In addition, an aggregate of 1,234,923 shares of our common stock have been granted under the 2014 Plan. The purpose of the 2014 Plan is to provide financial incentives for selected directors, employees, advisers, and consultants of Cardax and/or its subsidiaries, thereby promoting the long-term growth and financial success of the Company.

Equity Compensation Plan Information

The following table summarizes information as of March 28, 2016 about our outstanding stock options and shares of common stock reserved for future issuance under our existing equity compensation plans.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	34,167,354	\$ 0.47	9,971,514
Equity compensation plans not approved by security holders	-	-	-
Total	34,167,354	\$ 0.47	9,971,514

Recent Sales of Unregistered Securities

We entered into separate subscription agreements, registration rights agreements and warrant purchase agreements (each, a “Purchase Agreement”), by and between the Company and investors (each a “Purchaser” and collectively, the “Purchasers”) pursuant to which the Company issued and sold to the Purchasers shares of the Company’s common stock and Class D Warrants and E Warrants (each, a “Warrant” and, collectively, the “Warrants”) to purchase shares of the Company’s common stock.

Under the Purchase Agreements, each of the Purchasers purchased units (the “Unit”) at price per Unit of \$0.30 that consisted of: (A) one (1) share of the Company’s common stock, (B) two (2) Class D warrants, each to purchase one (1) share of the Company’s common stock at a price per share of \$0.10, and (C) one (1) Class E warrant to purchase three-quarters (3/4) of one (1) share of the Company’s common stock at a price per share of \$0.1667. The Class D warrants and the Class E warrants will expire March 31, 2020. In the year ended December 31, 2015, we sold an aggregate of 6,020,725 Units for an aggregate purchase price of \$1,806,222. No placement agent or broker dealer was used or participated in any offering or sale of such Units. On September 8, 2015, we engaged a broker dealer to assist in an offering of our securities as a placement agent. Any future offering of securities may be on the same terms as the sale of the Units or on other terms.

The offering of the Units was made in a transaction that is exempt from the registration requirements of the Securities Act, pursuant to Section 4(a)(2) thereof and the provisions of Regulation D or Regulation S that is promulgated under the Securities Act. The Company may continue to offer securities and may use a placement agent or broker dealer in any such offering.

This Annual Report on Form 10-K does not constitute an offer to sell, or a solicitation to purchase, any our securities.

Under the terms of the Registration Rights Agreement, the Company has agreed to register the common stock that is issued in the Unit and the shares underlying the Warrants shortly after March 31, 2016 or, if earlier, in connection with any registration rights that may be granted by us in an offering of securities of \$250,000 or more on or prior to March 31, 2016 (a "Qualified Financing"). The Subscription Agreement also includes "most favored nation" rights to the purchasers of the Units in the event the Company issues stock on terms more favorable to the purchaser in a Qualified Financing.

The foregoing summary of the Subscription Agreement, Registration Rights Agreement, and Warrants does not purport to be complete and is qualified in its entirety by reference to the full text of such agreements, which were filed with our Current Report on Form 8-K on March 9, 2015.

On April 20, 2015, we issued a warrant to a service provider to purchase 50,000 shares of our common stock at \$0.30 per share, which expires March 31, 2020.

On October 19, 2015, we issued a service provider 100,000 shares of our common stock. The total fair value of this stock on the date of issuance was \$45,000. These shares vested immediately.

On October 26, 2015, we issued 25,556 shares of our common stock in connection with the cashless exercise of a stock option for 41,851 shares of our common stock at \$0.155 per share with 16,295 shares of our common stock withheld with an aggregate fair market value equal to the aggregate exercise price.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

During each month within the fourth quarter of the fiscal year ended December 31, 2015, neither we nor any "affiliated purchaser," as that term is defined in Rule 10b-18(a)(3) under the Exchange Act, repurchased any of our common stock or other securities.

ITEM 6. SELECTED FINANCIAL DATA.

We are a "smaller reporting company," and, accordingly, we are not required to provide the information required by this Item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The financial data discussed below is derived from our audited consolidated financial statements for the fiscal years ended December 31, 2015 and 2014, which are found elsewhere in this Annual Report on Form 10-K. Our consolidated financial statements are prepared and presented in accordance with generally accepted accounting principles in the United States. The financial data discussed below is only a summary and investors should read the following discussion and analysis of our financial condition and results of our operations in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Our actual results and the timing of events may differ materially from those contained in these forward-looking statements due to a number of factors, including those discussed in the section entitled "Risk Factors," and elsewhere in this Annual Report on Form 10-K.

Corporate Overview and History

We acquired Pharma and its life science business through the merger of Cardax Sub, our wholly-owned transitory subsidiary, with and into Pharma on February 7, 2014 (the “Merger”), and a stock purchase agreement. As a result of these transactions, Pharma became our wholly-owned subsidiary. The only consideration that we paid under the stock purchase agreement and the Merger was shares of our common stock. On May 31, 2013, Pharma acquired all of the assets and assumed all of the liabilities of Holdings. Accordingly, we have two predecessors: Pharma and Pharma’s predecessor, Holdings. Prior to the February 7, 2014 effective date of the Merger, we operated under the name “Koffee Korner Inc.” and our business was limited to a single location retailer of specialty coffee located in Houston, Texas. On the effective date of the Merger, we divested our coffee business and now exclusively continue Pharma’s life sciences business. On December 30, 2015, our former principal stockholder, Holdings, merged with and into us (the “Holdings Merger”). There was not any cash consideration exchanged in the Holdings Merger. Upon the closing of the Holdings Merger, the stockholders of Holdings received an aggregate number of shares and warrants to purchase shares of our common stock equal to the aggregate number of shares of our common stock that were held by Holdings on the date of the closing of the Holdings Merger. Our restricted shares of common stock held by Holdings were cancelled upon the closing of the Holdings Merger. Accordingly, there was not any change to our fully diluted capitalization due to the Holdings Merger.

We currently devote substantially all of our efforts to developing consumer health and pharmaceutical products that we believe will provide many of the anti-inflammatory benefits of steroids or NSAIDs by targeting many of the same inflammatory pathways and mediators, but with exceptional safety profiles. The safety and efficacy of the Company’s product candidates have not been directly evaluated in clinical trials or confirmed by the FDA.

We are devoting substantially all of our present efforts to establishing our business. Our planned principal operations have not commenced and, accordingly, no revenue has been derived therefrom. We own intellectual property that we are marketing in varying stages worldwide. Our initial revenue generating opportunities are from our strategic alliances, including an exclusive license of our rights related to the development and commercialization of human consumer health products containing or utilizing a nature-identical form of astaxanthin and a collaboration related to proprietary formulations of astaxanthin. We also plan to pursue pharmaceutical applications of astaxanthin and related compounds.

At present we are not able to estimate if or when we will be able to generate sustained revenues. Our auditors have included in their report on our consolidated financial statements a “going concern” explanatory paragraph; that is to say, our consolidated financial statements have been prepared assuming that we will continue as a going concern. Given our recurring losses from operations, there is substantial doubt of our ability to continue as a going concern.

Results of Operations

Results of Operations for the Years Ended December 31, 2015 and 2014:

The following table reflects our operating results for the years ended December 31, 2015 and 2014:

Operating Summary	Year ended December 31, 2015	Year ended December 31, 2014	Change
Revenues	\$ -	\$ -	\$ -
Operating Expenses	(4,401,100)	(16,881,963)	12,480,863
Net Operating Loss	(4,401,100)	(16,881,963)	12,480,863
Other Income (Expenses)	143,225	(112,662)	255,887
Net Loss	<u>\$ (4,257,875)</u>	<u>\$ (16,994,625)</u>	<u>\$ 12,736,750</u>

Operating Summary

We are a pre-revenue company with limited operations and had no revenues for the years ended December 31, 2015 and 2014.

Operating expenses were \$4,401,100 and \$16,881,963 for the years ended December 31, 2015 and 2014, respectively. Included in operating expenses were \$1,918,183 and \$11,667,361 in stock based compensation for the years ended December 31, 2015 and 2014, respectively. Other operating expenses primarily consisted of services provided to the Company, including payroll and consultation, for research and development, and administration. These expenses were paid in accordance with agreements entered into with each consultant, employee, or service provider.

Other income (expenses), net, were \$143,225 and \$(112,662) for the years ended December 31, 2015 and 2014, respectively. For the year ended December 31, 2015, other income primarily consisted of a change in estimated accrued liabilities of \$48,204 and a gain on the sale of assets of \$95,000. For the year ended December 31, 2014, other expenses primarily consisted of interest expense on notes payable of \$112,450.

Assets and Liabilities

Assets were \$852,078 and \$1,547,091 as of December 31, 2015 and 2014, respectively. The decrease was primarily due to an inventory impairment of \$958,575 offset by a cash increase of \$287,714 in the year ended December 31, 2015. At December 31, 2015, cash totaled \$323,410. Negative working capital of \$4,186,301 as of December 31, 2015, was primarily due to accrued payroll and paid time off of \$3,468,610, accrued Board of Director fees and related consultation of \$418,546, and accounts payable of \$662,803, less cash of \$323,410. The accrual of payroll and Board of Director fees and related consultation, which occurred from January 2008 to December 2013, was due to significant capital constraints, and was selected in favor of layoffs or furloughs in order to maximize employee and director retention. In 2013 and 2014, the Company initiated repayment on these accrued amounts, utilizing approximately 5% to 10% of proceeds from various financings and plans to continue a structured repayment of the outstanding amounts over time as financing permits.

Liquidity and Capital Resources

Since our inception, we have sustained operating losses and have used cash raised by issuing securities in our operations. During the years ended December 31, 2015 and 2014, we used cash in operating activities of \$1,506,237 and \$5,695,231, respectively, and incurred a net loss of \$4,257,875 and \$16,994,625, respectively.

As of December 31, 2015, we had a U.S. federal income tax net operating loss carryforward of \$30,171,769. The net operating losses may be available to offset our future taxable income to the extent permitted under the Internal Revenue Code.

We require additional financing in order to continue to fund our operations, and pay existing and future liabilities and other obligations. To conserve cash resources, we agreed with our employees, executives, and certain vendors to pay any compensation due during any calendar quarter that has not been paid in cash in the form of shares of our common stock or stock options, as described in the Current Report on Form 8-K dated July 7, 2015. On March 28, 2016, we furloughed all of our employees and independent contractors indefinitely and arranged with our Chief Executive Officer, David G. Watumull; our Chief Financial Officer, John B. Russell; and our Vice President, Operations, David M. Watumull, to continue their services for cash compensation equal to the minimum wage. We continue to assess our commercial opportunities, which may include licensing our intellectual property or developing products with others, and may re-engage furloughed employees and contractors from time to time to the extent their services are required at cash compensation equal to the hourly minimum wage. In addition, each of the directors has agreed, effective April 1, 2016, to suspend any additional equity compensation, until otherwise agreed by the Company. In addition, we have deferred payment of other trade payables.

It is estimated that our limited available cash resources as of the date of this Annual Report on Form 10-K, would be sufficient to continue operations on a limited budget only through May 15, 2016. In addition to the \$1,806,000 raised during the year ended December 31, 2015, we intend to raise additional capital that would fund our operations through at least December 31, 2016. We are currently negotiating the terms of additional financing with investors and are considering a private placement of our common stock and warrants to purchase common stock. Any financing transaction could also, or in the alternative, include the issuance of our debt or convertible debt securities. There can be no assurance that a financing transaction would be available to us on terms and conditions that we determined are acceptable.

We cannot give any assurance that we will in the future be able to achieve a level of profitability from the sale of future products or otherwise to sustain our operations. These conditions raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on recoverability and reclassification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Any inability to so obtain additional financing on acceptable terms will materially and adversely affect us, including requiring us to significantly further curtail or cease business operations altogether.

Our working capital and capital requirements at any given time depend upon numerous factors, including, but not limited to:

- the progress of research and development programs;
- the level of resources that we devote to the development of our technologies, patents, marketing and sales capabilities; and
- revenues from the sale of any products or license revenues and the cost of any production or other operating expenses.

We have funded our research and development primarily by issuing convertible debt and equity securities in several separate private placements of securities.

On January 3, 2014, Pharma received total proceeds from the sale of convertible unsecured promissory notes of \$2,076,000.

Upon the consummation of the Merger, the outstanding principal amount of the senior secured convertible promissory notes issued by Pharma in 2013, consisting of (a) the aggregate principal amount of approximately \$3,648,244 for notes exchanged with Holdings on May 31, 2013, and (b) the aggregate principal amount of \$4,840,792 for notes issued by Pharma during the year ended December 31, 2013, together in the aggregate principal amount of \$8,489,036, plus all accrued interest thereon, was automatically converted into an aggregate number of 14,446,777 shares of our common stock and warrants, issued by Cardax, to purchase an aggregate of 14,446,777 shares of our common stock at an exercise price equal to \$0.625 that expire on February 7, 2019.

Upon the consummation of the Merger, the outstanding principal amount of the convertible unsecured promissory notes issued by Pharma in 2014, consisting of the aggregate principal amount of \$2,076,000 plus all accrued interest thereon, was automatically converted into an aggregate number of 3,353,437 shares of our common stock and warrants to purchase an aggregate of 3,321,600 shares of our common stock at an exercise price equal to \$0.625 that expire on February 7, 2019.

In addition, upon the consummation of the Merger we issued and sold an aggregate of 6,276,960 shares of our common stock and warrants, that expire on February 7, 2019, to purchase an aggregate of 6,276,960 shares of our common stock at a price per share equal to \$0.625, for aggregate gross cash proceeds of \$3,923,100.

During the year ended December 31, 2015, we sold securities in a self-directed offering in the aggregate amount of \$1,806,222 at \$0.30 per unit, which included the conversion of a \$30,000 note issued on January 28, 2015 and \$222 in accrued interest. Each unit consisted of one share of our common stock, two Class D warrants, each to purchase one share of our common stock at \$0.10 per share, which expire March 31, 2020, and one Class E warrant to purchase three-fourths of one share of our common stock at \$0.1667 per share, which expires March 31, 2020. In aggregate, we issued 6,020,725 shares of our common stock, Class D warrants to purchase 12,041,450 shares of our common stock, and Class E warrants to purchase 4,515,554 shares of our common stock.

We will incur ongoing recurring expenses associated with professional fees for accounting, legal, and other expenses for annual reports, quarterly reports, proxy statements and other filings under the Exchange Act. We estimate that these costs will likely be in excess of \$250,000 per year for the next few years. These obligations will reduce our ability and resources to fund other aspects of our business. We hope to be able to use our status as a public company to increase our ability to use non-cash means of settling obligations and compensate certain independent contractors who provide professional services to us, although there can be no assurances that we will be successful in any of those efforts.

The following is a summary of our cash flows provided by (used in) operating, investing and financing activities during the periods indicated:

Cash Flow Summary	Year ended Dec. 31, 2015	Year ended Dec. 31, 2014
Net Cash Used in Operating Activities	\$ (1,506,237)	\$ (5,695,231)
Net Cash Provided by (Used in) Investing Activities	(12,049)	59,127
Net Cash Provided by Financing Activities	1,806,000	5,449,390
Net Cash Increase (Decrease) for Period	287,714	(186,714)
Cash at Beginning of Year	35,696	222,410
Cash at End of Year	<u>\$ 323,410</u>	<u>\$ 35,696</u>

Cash Flows from Operating Activities

During the years ended December 31, 2015 and 2014, our operating activities primarily consisted of payments to, or accruals for payments to, employees, directors, and consultants, for services related to research and development and administration. The decrease in net cash used in operating activities of \$4,188,994 in the year ended December 31, 2015, was primarily attributable to a combination of (i) a decrease in professional and financing expenses in the aggregate amount of \$1,959,263, and (ii) a decrease in cash payments of accrued payroll, accounts payable, accrued interest, and fees payable to directors in the aggregate amount of \$1,544,303.

Cash Flows from Investing Activities

During the years ended December 31, 2015 and 2014, our investing activities were primarily related to proceeds from the sale of equipment and capitalization of patent costs.

Cash Flows from Financing Activities

During the years ended December 31, 2015 and 2014, our financing activities consisted of various transactions in which we raised proceeds through the issuance of debt and common stock. Because of the nature of our business, capital is required to support research and development costs, as well as, our normal operating costs.

Our existing liquidity is not sufficient to fund our operations, anticipated capital expenditures, working capital and other financing requirements for the foreseeable future. We will need to seek to obtain additional debt or equity financing, especially if we experience downturns or cyclical fluctuations in our business that are more severe or longer than anticipated, or if we experience significant increases in the cost of components and manufacturing, or increases in our expense levels resulting from being a publicly-traded company. If we attempt to obtain additional debt or equity financing, we cannot assure you that such financing will be available to us on favorable terms, or at all.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases*. The main provisions of ASU No. 2016-02 require management to recognize lease assets and lease liabilities for all leases. ASU 2016-02 retains a distinction between finance leases and operating leases. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous leases guidance. The result of retaining a distinction between finance leases and operating leases is that under the lessee accounting model, the effect of leases in the statement of comprehensive income and the statement of cash flows is largely unchanged from previous GAAP. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently assessing the impact of this ASU on the Company’s consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Income taxes*. The provisions of ASU No. 2015-17 simplify the presentation of deferred income taxes, the amendments in this ASU require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in this Update apply to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this Update. The amendments in this ASU are effective for the annual period ending after December 15, 2016, including interim periods within those fiscal years. The Company does not believe that the adoption of this update will have a significant impact to the Company’s consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory—Simplifying the Measurement of Inventory*. The provisions of ASU No. 2015-11 clarify measurement of inventory at the lower of cost or market and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amendments in this ASU are effective for the annual period ending after December 15, 2016, including interim periods within those fiscal years. The Company does not believe that the adoption of this update will have a significant impact to the Company’s consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern*. The provisions of ASU No. 2014-15 require management to assess an entity’s ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management’s plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management’s plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). The amendments in this ASU are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company is currently assessing the impact of this ASU on the Company’s consolidated financial statements.

Our management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material effect on the consolidated financial statements filed with this annual report.

Off-Balance Sheet Arrangements

There are no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are a “smaller reporting company,” and, accordingly, we are not required to provide the information required by this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The consolidated financial statements required by this Item, together with the report of our independent registered public accounting firm, KBL, LLP, begin on page F-1, immediately following the signatures to this annual report. Please refer to Item 15 of this report for an index of the consolidated financial statements included in this annual report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Internal control over financial reporting is a process designed 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 and includes those policies and procedures that (a) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (b) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the Company are being made only in accordance with authorizations of the our management and directors; and (c) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company’s assets that could have a material effect on the financial statements. Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2015.

Changes in Internal Controls over Financial Reporting

There were no changes in the Company’s internal control over financial reporting during the fiscal year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

On March 28, 2016, the Company furloughed all of its employees and independent contractors indefinitely and arranged with its Chief Executive Officer, David G. Watumull; its Chief Financial Officer, John B. Russell; and its Vice President, Operations, David M. Watumull, to continue their services for cash compensation equal to the minimum wage. The Company continues to assess its commercial opportunities, which may include licensing its intellectual property or developing products with others, and may re-engage furloughed employees and contractors from time to time to the extent their services are required at cash compensation equal to the hourly minimum wage. In addition, each of the directors has agreed, effective April 1, 2016, to suspend any additional equity compensation, until otherwise agreed by the Company.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Set forth below is a list of the names, ages and positions of our directors and executive officers.

Name	Age	Position(s)
Nicholas Mitsakos	56	Executive Chairman of the Board of Directors
David G. Watumull	66	President, Chief Executive Officer, and Director
George W. Bickerstaff, III	60	Director
Terence A. Kelly, Ph.D.	54	Director
John B. Russell	43	Chief Financial Officer and Treasurer
Richard M. Morris	55	Secretary
David M. Watumull	34	Vice President, Operations, Assistant Treasurer, and Assistant Secretary

Biographies of Directors and Executive Officers

Nicholas Mitsakos has served as our Executive Chairman of the Board since February 7, 2014. Mr. Mitsakos has served as the Executive Chairman of the Board of Pharma since its inception in May 2013, as Executive Chairman of the Board Holdings since May 2009, as Chairman of the Board of Holdings from May 2006 to May 2009, and as a Director of Holdings from its inception in March 2006 to May 2006. Mr. Mitsakos has served as the Chairman and Chief Executive Officer of Arcadia Holdings, Inc. since 1989, focusing on private equity and venture capital investments globally. He has also been a senior advisor to Sardis Capital, a London-based merchant bank since 2003, to Franklin Templeton China in Shanghai since 2001, and previously to Templeton International. Mr. Mitsakos has also served as a director of Meru Networks, Inc. since 2002, Chairman of IMEx Minerals, LLC since 2005, and Co-Chairman of Ubiquity Broadcasting Corporation since 2011. Mr. Mitsakos worked at Goldman Sachs in 1985 and Drexel Burnham Lambert from 1986 to 1989. He holds B.S. degrees in Computer Science and Microbiology from the University of Southern California, where he graduated first in his class, and an MBA from Harvard University. He taught at UCLA's Anderson School of Business from 1992 to 1998, and is also on the board of UCLA's Center for Cerebral Palsy within the UCLA Medical School. Mr. Mitsakos is also on the board of the Rehabilitation Hospital of the Pacific and a lecturer at the Harvard Innovation Center at Harvard University. Mr. Mitsakos provides valuable insight and leadership to our Board through his deep financial expertise and his longstanding history with the development of our business.

David G. Watumull has served as our Chief Executive Officer, President, and Director since February 7, 2014. Mr. Watumull has served as the Chief Executive Officer, President, and Director of Pharma since its inception in May 2013 and as the Chief Executive Officer, President, and Director of Holdings since its inception in March 2006. Mr. Watumull is a co-founder of Holdings and has over 20 years of experience as a biotechnology industry executive. From 2001 to 2006, Mr. Watumull served as President, Chief Executive Officer, and Director of Hawaii Biotech, Inc. Mr. Watumull was Executive Vice President of Aquasearch, Inc., a public astaxanthin consumer health company, from 1998 to 2000. From 1997 to 1998 he headed his own biotech research firm, Watumull & Co. From 1994 to 1997 he was a biotech research analyst, money manager, and investment banker at First Honolulu Securities. From 1992 to 1994 he led his own money management firm, Biovest, Inc. Prior to that, from 1982 to 1992, Mr. Watumull worked at Paine Webber in various capacities, including as a biotech money manager and investment executive. Mr. Watumull's extensive background in the biotechnology industry, his operational acumen, and his position of leadership since the founding of our business uniquely qualifies him to serve as a member of our Board.

George W. Bickerstaff, III has served as a Director since June 16, 2014. Mr. Bickerstaff is currently a Managing Director of M.M. Dillon & Co., LLC, which he joined in 2005. Prior to joining M.M. Dillon & Co., LLC, Mr. Bickerstaff held various positions with Novartis International AG, a global pharmaceuticals and consumer health company, including Chief Financial Officer of Novartis Pharma AG from October 2000 to May 2005. From December 1999 to September 2000, Mr. Bickerstaff served as Executive Vice President and Chief Financial Officer of Workscape, Inc. a provider of employee-related information services. From July 1998 to December 1999, Mr. Bickerstaff served as Executive Vice President and Chief Financial Officer of Uniscribe Professional Services, Inc., a nationwide provider of paper and technology-based document management solutions. From January 1998 to June 1998, Mr. Bickerstaff served as Executive Vice President and Chief Financial Officer of Intellisource Group, Inc., a provider of information technology solutions to the federal, state and local government and utility markets. From July 1997 to December 1997, Mr. Bickerstaff served as Vice President of Finance of Cognizant Corporation, a global business information services company. From January 1990 to June 1997, Mr. Bickerstaff served in various senior finance roles, including Chief Financial Officer of IMS Healthcare, a global business information services company in the healthcare and pharmaceutical industries. Prior to that, Mr. Bickerstaff held various finance, audit and engineering positions with the Dun & Bradstreet Corporation and General Electric Company. Mr. Bickerstaff has been a member of the board of directors of CareDx, Inc., a company that develops, markets, and delivers diagnostic surveillance solutions for organ transplant recipients, since April 2014. Mr. Bickerstaff was a member of the board of directors of Vion Pharmaceuticals, Inc., from June 2005 to March 2010. Mr. Bickerstaff's nonprofit activities include serving on the board of directors of the International Vaccine Institute, the International Centre for Missing and Exploited Children, The Center for Disease Dynamics, Economics & Policy and The Global Alliance for Vaccines and Immunization. Mr. Bickerstaff holds a B.S. in Engineering and a B.A. in Business Administration from Rutgers University (1978). Mr. Bickerstaff's experience through various roles in establishing the strategic, operational, and financial direction of numerous private and public companies, including those in the pharmaceutical industry, will be instrumental in enabling our Board to implement our strategic plan.

Terence A. Kelly, Ph.D. has served as a Director since June 16, 2014. He has over 20 years of experience as a scientist and executive in the pharmaceutical industry starting as a medicinal chemist in 1990. Dr. Kelly is currently the President and Chief Executive Officer of CoMentis, Inc. and a founder of Kelly Pharma Research Consulting, LLC. From 1990 to 2009, Dr. Kelly served in various scientific and executive positions at Boehringer Ingelheim, where after a successful early career developing LFA-1 antagonists, he led its US-based medicinal chemistry department, which included 145 scientists in the high throughput screening, computational chemistry, structural biology, combinatorial chemistry and medicinal chemistry groups. Dr. Kelly holds a B.S. degree in Chemistry at Rensselaer Polytechnic Institute (1982) and a Ph.D. degree in Chemistry at the University of Texas at Austin (1988). He completed postdoctoral work in natural products synthesis at Yale University (1988-1990) and holds an MBA from New York University, Stern School of Business (1998). Dr. Kelly is the co-author of over 25 scientific publications and serves on the College of Natural Sciences Advisory Council for the University of Texas. Dr. Kelly's scientific training and his track record of delivering high quality compounds into advanced clinical studies provide valuable skills and knowledge to our Board.

John B. Russell, CPA, has served as our Chief Financial Officer and Treasurer since February 7, 2014. Mr. Russell has also served as the Chief Financial Officer and Treasurer of Pharma and Holdings since July 2013. Mr. Russell is the founder of JBR Business Solutions, LLC and has served as its President since 2010. Mr. Russell has over 20 years of accounting, finance, operations, and SEC reporting experience in biopharmaceutical and high-tech industries. From 2010 to the present, he has served as Chief Financial Officer for various privately-held start-up companies. Mr. Russell was in charge of the Business Advisory Services for the Grant Thornton Honolulu office from 2006 to 2010. From 2005 to 2006, Mr. Russell worked at a consulting company as the Operations Consulting - Financial Management lead, advising Cisco Systems, Inc. Mr. Russell was the General Accounting Manager of the publicly traded company Scios Inc. from 2003 to 2005, where he was in charge of SEC reporting and internal controls. Mr. Russell was the Controller for several portfolio companies in the venture capital firm, Raza Foundries, Inc., from 2001 to 2002, and the General Accounting Manager for inSilicon Corporation, a public company, from 2000 to 2001. Previous to that, Mr. Russell was an auditor at PricewaterhouseCoopers LLP from 1995 to 2000. Mr. Russell is a licensed CPA in Hawaii and has a B.A. in Economics/Accounting from Claremont McKenna College.

Richard M. Morris has served as our Secretary since February 7, 2014. Mr. Morris has served as Assistant Secretary of Pharma since May 2013 and Assistant Secretary of Holdings since July 2013. Mr. Morris is a Partner at Herrick, Feinstein LLP, our legal counsel ("Herrick"). As a partner of Herrick, Mr. Morris represents a variety of clients, primarily in corporate matters. Prior to becoming a lawyer, Mr. Morris was an auditor with the Commodities Exchange in New York and later focused on operations and financial management at Kidder Peabody. He also was the U.S. Audit Manager for the financial division for a diversified Australian company. Mr. Morris has a B.S. in Accounting from New York University (1982) and a J.D. from Fordham University School of Law (1990), with bar admissions in New York and Connecticut.

David M. Watumull has served as our Vice President, Operations, Assistant Treasurer, and Assistant Secretary since February 7, 2014. Mr. Watumull has served as Vice President, Operations of Pharma since its inception in May 2013, Assistant Treasurer and Assistant Secretary of Pharma since July 2013, and Secretary and Treasurer of Pharma from its inception in May 2013 to July 2013. Mr. Watumull has served as Vice President, Operations, Assistant Treasurer, and Assistant Secretary of Holdings since July 2013, and previously as Director, Operations and Finance from 2009 to 2013, Operations Manager from 2008 to 2009, and Program Manager from its inception in 2006 to 2009. Mr. Watumull heads day-to-day company operations related to accounting, banking, budgeting, leasing, insurance, debt/equity transactions and due diligence, capitalization structure, reporting, corporate governance, contracting and related legal matters, intellectual property, human resources, front office, facilities and equipment, and information technology. Mr. Watumull also manages the relationships, timelines, and budgets of development partners, contractors, and regulatory consultants associated with the production and testing of Cardax products. Mr. Watumull was previously Program Manager at Hawaii Biotech, Inc. from 2005 to 2006, Project Coordinator from 2004 to 2005, and Information Technology Associate / Manager from 2002 to 2004. Mr. Watumull also worked at Aquasearch, Inc. from 2000 to 2001 in various capacities including Medical Information Specialist and Information Technology Associate. Mr. Watumull graduated first in his high school class and studied Electrical Engineering at the University of Hawaii.

Executive officers are appointed by our Board of Directors. Each executive officer holds his or her office until he or she resigns, is removed by our Board of Directors or his or her successor is elected and qualified. Directors are elected annually by our stockholders at the annual meeting. Each director holds his or her office until his or her successor is elected and qualified or his or her earlier resignation or removal.

There have been no material changes to the procedures by which security holders may recommend nominees to our Board of Directors since our last annual report.

Family Relationships

David G. Watumull is the father of David M. Watumull. There are no other family relationships among any of our officers or directors.

Involvement in Certain Legal Proceedings

To the best of our knowledge, none of our directors or executive officers has been convicted in a criminal proceeding, excluding traffic violations or similar misdemeanors, or has been a party to any judicial or administrative proceeding during the past ten years that resulted in a judgment, decree, or final order enjoining the person from future violations of, or prohibiting activities subject to, federal or state securities laws, or a finding of any violation of federal or state securities laws, except for matters that were dismissed without sanction or settlement. Except as set forth in our discussion below in “Certain Relationships and Related Transactions, and Director Independence – Transactions with Related Persons,” none of our directors, director nominees, or executive officers has been involved in any transactions with us or any of our directors, executive officers, affiliates, or associates which are required to be disclosed pursuant to the rules and regulations of the Commission.

Code of Ethics

Our Code of Business Conduct and Ethics, effective as of February 7, 2014 (the “Code of Ethics”), contains the ethical principles by which our Chief Executive Officer and Chief Financial Officer, among others, are expected to conduct themselves when carrying out their duties and responsibilities. A copy of our Code of Ethics may be found on our website at www.cardaxpharma.com. We will provide a copy of our Code of Ethics to any person, without charge, upon request, by writing to David G. Watumull, Cardax, Inc., 2800 Woodlawn Drive, Suite 129, Honolulu, Hawaii 96822.

Board Committees

We are not required under the Securities and Exchange Act to maintain any committees of our Board of Directors. We have formed certain committees of our board as a matter of preferred corporate practices.

We have an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below.

Audit Committee. Our audit committee oversees a broad range of issues surrounding our accounting and financial reporting processes and audits of our consolidated financial statements, including the following:

- monitors the integrity of our financial statements, our compliance with legal and regulatory requirements, our independent registered public accounting firm’s qualifications and independence, and the performance of our internal audit function and independent registered public accounting firm;
- assumes direct responsibility for the appointment, compensation, retention and oversight of the work of any independent registered public accounting firm engaged for the purpose of performing any audit, review or attest services and for dealing directly with any such accounting firm;
- provides a medium for consideration of matters relating to any audit issues; and
- prepares the audit committee report that the rules require be included in our filings with the SEC.

The members of our audit committee are George W. Bickerstaff, III (Chairperson) and Terence A. Kelly, Ph.D. Our audit committee has a written charter available on our website at www.cardaxpharma.com.

Compensation Committee. Our compensation committee reviews and recommends policy relating to compensation and benefits of our officers, directors and employees, including reviewing and approving corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other senior officers, evaluating the performance of these persons in light of those goals and objectives and setting compensation of these persons based on such evaluations. The compensation committee reviews and evaluates, at least annually, the performance of the compensation committee and its members, including compliance of the compensation committee with its charter.

The members of our compensation committee are Terence A. Kelly, Ph.D. (Chairperson) and George W. Bickerstaff, III. Our compensation committee has a written charter available on our website at www.cardaxpharma.com.

Nominating and Corporate Governance Committee. The nominating and corporate governance committee oversees and assists our Board of Directors in identifying, reviewing and recommending nominees for election as directors; evaluating our Board of Directors and our management; developing, reviewing and recommending corporate governance guidelines and a corporate code of business conduct and ethics; and generally advises our Board of Directors on corporate governance and related matters.

The members of our nominating and corporate governance committee are Terence A. Kelly, Ph.D. (Chairperson) and George W. Bickerstaff, III. Our nominating and corporate governance committee has a written charter available on our website at www.cardaxpharma.com.

Conflicts of Interest

Certain potential conflicts of interest are inherent in the relationships between our officers and directors and us.

From time to time, one or more of our affiliates may form or hold an ownership interest in and/or manage other businesses both related and unrelated to the type of business that we own and operate. These persons expect to continue to form, hold an ownership interest in and/or manage additional other businesses which may compete with our business with respect to operations, including financing and marketing, management time and services and potential customers. These activities may give rise to conflicts between or among the interests of us and other businesses with which our affiliates are associated. Our affiliates are in no way prohibited from undertaking such activities, and neither us nor our stockholders will have any right to require participation in such other activities.

Further, because we intend to transact business with some of our officers, directors and affiliates, as well as with firms in which some of our officers, directors or affiliates have a material interest, potential conflicts may arise between the respective interests of us and these related persons or entities. We believe that such transactions will be effected on terms at least as favorable to us as those available from unrelated third-parties.

With respect to transactions involving real or apparent conflicts of interest, we have adopted policies and procedures which require that: (i) the fact of the relationship or interest giving rise to the potential conflict be disclosed or known to the directors who authorize or approve the transaction prior to such authorization or approval; and (ii) the transaction be fair and reasonable to us at the time it is authorized or approved by our directors.

ITEM 11. EXECUTIVE COMPENSATION.

The following sets forth information with respect to the compensation awarded or paid to David G. Watumull, our Chief Executive Officer, Nicholas Mitsakos, our Executive Chairman of the Board, and David M. Watumull, our Vice President, Operations, for all services rendered in all capacities to the Company and its predecessors during the fiscal years ending December 31, 2014 and 2015. These three executive officers are referred to as the “named executive officers” throughout this Annual Report on Form 10-K. In addition, the following sets forth information with respect to the compensation awarded or paid to our two highest compensated individuals not serving as executive officers, Gilbert M. Rishton, our Chief Science Officer, and Timothy J. King, our Vice President, Research, for all services rendered in all capacities to the Company and its predecessors during the fiscal years ending December 31, 2014 and 2015.

Compensation of Executive Officers

The following table sets forth information regarding each element of compensation that we paid or awarded to our named executive officers, and our two highest compensated individuals not serving as executive officers, for the two fiscal years ended December 31, 2014 and 2015, which includes cash compensation, stock options awarded in lieu of cash compensation, and all other compensation:

Name	Year	Cash Comp. ⁽¹⁾	Stock Options in Lieu of Cash		All Other Comp. ⁽³⁾	Total
			Comp. ⁽²⁾			
David G. Watumull Chief Executive Officer	2014	\$ 475,000 ⁽⁴⁾	\$ -	\$ 20,337	\$ 495,337	
	2015	\$ 88,807 ⁽⁵⁾⁽⁶⁾	\$ 205,424 ⁽⁵⁾	\$ 16,151	\$ 310,382	
Nicholas Mitsakos Executive Chairman	2014	\$ 265,000 ⁽⁷⁾	\$ -	\$ -	\$ 265,000	
	2015	\$ 9,231 ⁽⁸⁾	\$ 167,884 ⁽⁷⁾	\$ -	\$ 177,115	
David M. Watumull Vice President, Operations	2014	\$ 195,000 ⁽⁹⁾	\$ -	\$ 6,606	\$ 201,606	
	2015	\$ 63,230 ⁽¹⁰⁾	\$ 113,308	\$ 5,917	\$ 182,455	
Gilbert M. Rishton Chief Science Officer	2014	\$ 225,000 ⁽¹¹⁾	\$ -	\$ 966	\$ 225,966	
	2015	\$ 72,461 ⁽¹²⁾	\$ 135,232	\$ 526	\$ 208,219	
Timothy J. King Vice President, Research	2014	\$ 195,000 ⁽¹³⁾	\$ -	\$ 522	\$ 195,522	
	2015	\$ 63,230 ⁽¹⁴⁾	\$ 113,308	\$ 281	\$ 176,819	

(1) The amounts disclosed refer to cash compensation.

(2) The amounts disclosed refer to stock options awarded in lieu of cash compensation.

(3) The amounts disclosed refer to imputed income in connection with certain benefits and/or insurance premiums paid in lieu of additional cash compensation.

(4) The amount disclosed also includes payment of accrued compensation to Mr. David G. Watumull.

(5) The annual salary of Mr. David G. Watumull was decreased to \$225,000 effective April 2015.

(6) On March 28, 2016, Mr. David G. Watumull was furloughed and agreed to continue service as Chief Executive Officer for cash compensation equal to the minimum wage.

(7) The amount disclosed also includes payment of accrued compensation to Mr. Mitsakos.

(8) The annual compensation of Mr. Mitsakos as the Executive Chairman was decreased to \$150,000 effective April 2015, payable quarterly in arrears in the form of equity. In addition, Mr. Mitsakos has agreed, effective April 1, 2016, to suspend any additional equity compensation, until otherwise agreed by the Company.

(9) The amount disclosed also includes payment of accrued compensation to Mr. David M. Watumull.

(10) On March 28, 2016, Mr. David M. Watumull was furloughed and agreed to continue service as Vice President, Operations for cash compensation equal to the minimum wage.

(11) The amount disclosed also includes payment of accrued compensation to Mr. Rishton.

(12) On March 28, 2016, Mr. Rishton was furloughed and may from time to time be re-engaged to the extent his services are required at cash compensation equal to the hourly minimum wage.

(13) The amount disclosed also includes payment of accrued compensation to Mr. King.

(14) On March 28, 2016, Mr. King was furloughed and may from time to time be re-engaged to the extent his services are required at cash compensation equal to the hourly minimum wage.

Outstanding Equity Awards to Executive Officers at Fiscal Year-End 2015

The following table sets forth information regarding outstanding option awards to our named executive officers as of December 31, 2015:

Name	Option awards ⁽¹⁾⁽²⁾					Option expiration date
	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable	Number of securities underlying unexercised unearned options	Option exercise price (\$)		
David G. Watumull	1,750,588	-	-	\$ 0.155		February 7, 2024
David G. Watumull	4,941,845	-	-	\$ 0.625		February 7, 2024
David G. Watumull	468,498 ⁽³⁾	-	-	\$ 0.32		June 30, 2020
David G. Watumull	390,686 ⁽³⁾	-	-	\$ 0.20		June 30, 2020
David G. Watumull	89,523 ⁽³⁾	-	-	\$ 0.49		September 30, 2020
David G. Watumull	137,675 ⁽³⁾	-	-	\$ 0.27		December 31, 2020
Nicholas Mitsakos	1,496,700	-	-	\$ 0.155		February 7, 2024
Nicholas Mitsakos	2,762,121	-	-	\$ 0.625		February 7, 2024
Nicholas Mitsakos	263,736 ⁽³⁾	-	-	\$ 0.32		June 30, 2020
Nicholas Mitsakos	288,462 ⁽³⁾	-	-	\$ 0.20		June 30, 2020
Nicholas Mitsakos	129,310 ⁽³⁾	-	-	\$ 0.49		September 30, 2020
Nicholas Mitsakos	170,455 ⁽³⁾	-	-	\$ 0.27		December 31, 2020

David M. Watumull	45,058	-	-	\$	0.155	February 7, 2024
David M. Watumull	2,388,554	-	-	\$	0.625	February 7, 2024
David M. Watumull	160,806 ⁽³⁾	-	-	\$	0.32	June 30, 2020
David M. Watumull	284,917 ⁽³⁾	-	-	\$	0.20	June 30, 2020
David M. Watumull	67,639 ⁽³⁾	-	-	\$	0.49	September 30, 2020
David M. Watumull	104,021 ⁽³⁾	-	-	\$	0.27	December 31, 2020

- (1) The type of securities underlying all outstanding option awards is our common stock.
- (2) None of our named executive officers have received stock awards.
- (3) Stock options awarded in lieu of cash compensation.

Compensation of Directors

Mr. Mitsakos, our Executive Chairman of the Board, received compensation for his services as a director as set forth under “Compensation of Executive Officers.”

The following table sets forth information regarding each element of compensation that we paid or awarded to our current independent directors for the two fiscal years ended December 31, 2014 and 2015:

Name	Year	Cash Comp.	Stock Awards	Total
George W. Bickerstaff, III	2014	\$ -	\$ 179,828 ⁽¹⁾	\$ 179,828
George W. Bickerstaff, III	2015	\$ -	\$ 58,333 ⁽²⁾	\$ 58,333
Terence A. Kelly	2014	\$ -	\$ 166,749 ⁽³⁾	\$ 166,749
Terence A. Kelly	2015	\$ -	\$ 58,333 ⁽⁴⁾	\$ 58,333

- (1) The amount disclosed represents compensation recognized in 2014, in accordance with elections made under 83(b) of the Internal Revenue Code, for stock awarded in connection with services provided by Mr. Bickerstaff as an independent director commencing in June 2014. The shares of common stock were subject to a risk of forfeiture and vested quarterly in arrears commencing on June 1, 2014.
- (2) The amount disclosed represents compensation recognized in 2015 for stock awarded in connection with services provided by Mr. Bickerstaff as an independent director. In addition, Mr. Bickerstaff has agreed, effective April 1, 2016, to suspend any additional equity compensation, until otherwise agreed by the Company.
- (3) The amount disclosed represents compensation recognized in 2014, in accordance with elections made under 83(b) of the Internal Revenue Code, for stock awarded in connection with services provided by Dr. Kelly as an independent director commencing in June 2014. The shares of common stock were subject to a risk of forfeiture and vested quarterly in arrears commencing on June 1, 2014.
- (4) The amount disclosed represents compensation recognized in 2015 for stock awarded in connection with services provided by Dr. Kelly as an independent director. In addition, Dr. Kelly has agreed, effective April 1, 2016, to suspend any additional equity compensation, until otherwise agreed by the Company.

The following table sets forth information regarding each element of compensation that we paid or awarded to our former independent directors for the two fiscal years ended December 31, 2014 and 2015:

Name	Year	Cash Comp.	Stock Awards	Total
Frank C. Herringer	2014	\$ 36,458 ⁽¹⁾	\$ 62,937 ⁽²⁾	\$ 99,395
Frank C. Herringer	2015	\$ -	\$ 23,787 ⁽³⁾	\$ 23,787
Tamar D. Howson	2014	\$ -	\$ 179,828 ⁽⁴⁾	\$ 179,828
Tamar D. Howson	2015	\$ -	\$ -	\$ -

- (1) The amount disclosed also includes payment of accrued compensation to Mr. Herringer.
- (2) The amount disclosed represents compensation recognized in 2014 for stock awarded in connection with continued services provided by Mr. Herringer as an independent director. The shares of common stock were subject to a risk of forfeiture and vested quarterly in arrears commencing on June 1, 2014.
- (3) The amount disclosed represents compensation recognized in 2015 for stock awarded in connection with continued services provided by Mr. Herringer as an independent director. The shares of common stock were subject to a risk of forfeiture and vested quarterly in arrears commencing on June 1, 2014.
- (4) The amount disclosed represents compensation recognized in 2014, in accordance with elections made under 83(b) of the Internal Revenue Code, for stock awarded in connection with services provided by Ms. Howson as an independent director commencing in June 2014. The shares of common stock were subject to a risk of forfeiture and vested quarterly in arrears commencing on June 1, 2014.

Outstanding Equity Awards to Directors at Fiscal Year-End 2015

Mr. Mitsakos, our Executive Chairman of the Board, received option awards for his services as a director as set forth under “Outstanding Equity Awards to Directors at Fiscal Year-End 2015.”

The following table sets forth information regarding outstanding stock awards to our independent directors as of December 31, 2015:

Name	Stock awards
	Number of securities awarded
George W. Bickerstaff, III	427,310 ⁽¹⁾
Terence A. Kelly	411,163 ⁽¹⁾

(1) All shares are fully vested.

Employment and Consulting Agreements

On February 7, 2014, we entered into employment agreements with each of Messrs. David G. Watumull, David M. Watumull, Gilbert M. Rishton, and Timothy J. King, which provided for employment for an initial term of one year, subject to renewal and earlier termination rights as provided in such agreements. These agreements provide for compensation terms and duration of employment as set forth in each such agreement. Such agreements include restrictive covenants concerning competition with us and solicitation of our employees and clients, if such individuals are terminated for cause as defined in such agreements.

On February 7, 2014, we entered into an Agreement for Services as the Executive Chairman with Nicholas Mitsakos, pursuant to which Mr. Mitsakos agreed to serve as our Executive Chairman. We agreed to pay Mr. Mitsakos an annual salary of \$240,000 for his services as an executive officer.

To conserve cash resources while seeking additional financing, we and our employees, including Messrs. David G. Watumull, David M. Watumull, Gilbert M. Rishton, and Timothy J. King, agreed to reduce cash compensation effective January 15, 2015. In addition, Mr. Mitsakos reduced his cash compensation to zero. The amount of an individual’s compensation that was not paid was deferred.

On June 30, 2015, the compensation arrangements of Messrs. David G. Watumull, David M. Watumull, Gilbert M. Rishton, and Timothy J. King were amended so that, effective after June 30, 2015, we had the right to pay any compensation due to such officer during any calendar quarter that was not paid in cash in the form of shares of our common stock or incentive stock options under the 2014 Plan. In addition, the amount of the unpaid cash compensation that accrued during the first and second quarters of 2015 was paid with incentive stock options under the 2014 Plan.

On June 30, 2015, the compensation arrangement with Mr. Mitsakos was amended so that, effective April 1, 2015, Mr. Mitsakos would receive an aggregate annual compensation equal to \$150,000, payable quarterly, in arrears, in the form of a grant of shares of our common stock or non-qualified stock options to purchase shares of our common stock under the 2014 Plan. In addition, the amount of the unpaid cash compensation that accrued during the first and second quarters of 2015 was paid with non-qualified stock options under the 2014 Plan.

On March 28, 2016, we furloughed all of our employees and independent contractors indefinitely and arranged with our Chief Executive Officer, David G. Watumull; our Chief Financial Officer, John B. Russell; and our Vice President, Operations, David M. Watumull, to continue their services for cash compensation equal to the minimum wage. We continue to assess our commercial opportunities, which may include licensing our intellectual property or developing products with others, and may re-engage furloughed employees and contractors from time to time to the extent their services are required at cash compensation equal to the hourly minimum wage. In addition, each of the directors has agreed, effective April 1, 2016, to suspend any additional equity compensation, until otherwise agreed by the Company.

2014 Equity Compensation Plan

Our 2014 Plan is administered by our compensation committee. The purpose of the 2014 Plan is to provide financial incentives for selected directors, employees, advisers, and consultants of Cardax and/or its subsidiaries, thereby promoting the long-term growth and financial success of the Company. The issuance of awards under the 2014 Plan is at the discretion of our compensation committee, which has the authority to determine the persons to whom any awards shall be granted and the terms, conditions and restrictions applicable to any award. Under the 2014 Plan, we may grant equity based incentive awards, including options, restricted stock, and other stock-based awards, to any directors, employees, advisers, and consultants that provide services to us or any of our subsidiaries. An aggregate of 45,420,148 shares of our common stock have been reserved for issuance under the 2014 Plan, which is subject to adjustment as described in such plan. As of March 28, 2016, there are 9,971,514 shares of common stock available for future awards under the 2014 Plan.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 201(d) of Regulation S-K regarding our 2014 Plan is outlined above in Item 5 of this Annual Report on Form 10-K.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding the ownership of our common stock as of March 28, 2016 for:

- each director;
- each person known by us to own beneficially 5% or more of our common stock;
- each officer named in the summary compensation table elsewhere in this report; and
- all directors and executive officers as a group.

The amounts and percentages of our common stock beneficially owned are reported on the basis of regulations of the SEC governing the determination of beneficial ownership of securities. Under the rules of the SEC, a person is deemed to be a “beneficial owner” of a security if that person has or shares “voting power,” which includes the power to vote or to direct the voting of such security, or “investment power,” which includes the power to dispose of or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities of which that person has the right to acquire beneficial ownership within 60 days. Under these rules more than one person may be deemed a beneficial owner of the same securities and a person may be deemed to be a beneficial owner of securities as to which such person has no economic interest.

Unless otherwise indicated below, to the best of our knowledge each beneficial owner named in the table has sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable.

Name	Amount of Beneficial Ownership of Common Stock	Percent of Common Stock ⁽¹⁾
Nicholas Mitsakos ⁽²⁾	6,941,266 ⁽³⁾	9.3%
George W. Bickerstaff, III ⁽⁴⁾	427,310 ⁽⁵⁾	0.6%
Terence A. Kelly, Ph.D. ⁽⁶⁾	411,163 ⁽⁷⁾	0.6%
David G. Watumull ⁽⁸⁾	8,237,979 ⁽⁹⁾	10.7%
David M. Watumull ⁽¹⁰⁾	3,050,995 ⁽¹¹⁾	4.2%
John B. Russell ⁽¹²⁾	166,203 ⁽¹³⁾	0.2%
All directors and executive officers as a group (6 persons)	19,234,916	22.5%

(1) Based on 69,087,955 shares of common stock issued and outstanding as of March 28, 2016.

(2) The address of Mr. Nicholas Mitsakos is c/o Cardax, Inc., 2800 Woodlawn Drive, Honolulu, Hawaii 96822. Mr. Mitsakos is the Executive Chairman of our Board of Directors.

(3) Represents (a) 1,496,700 shares of common stock issuable upon exercise by Mr. Mitsakos of options that are presently exercisable, at an exercise price of \$0.155 per share, (b) 2,762,121 shares of common stock issuable upon exercise by Mr. Mitsakos of options that are presently exercisable, at an exercise price of \$0.625 per share, (c) 263,736 shares of common stock issuable upon exercise by Mr. Mitsakos of options that are presently exercisable, at an exercise price of \$0.32 per share, (d) 288,462 shares of common stock issuable upon exercise by Mr. Mitsakos of options that are presently exercisable, at an exercise price of \$0.20 per share, (e) 129,310 shares of common stock issuable upon exercise by Mr. Mitsakos of options that are presently exercisable, at an exercise price of \$0.49 per share, (f) 170,455 shares of common stock issuable upon exercise by Mr. Mitsakos of options that are presently exercisable, at an exercise price of \$0.27 per share, (g) 219,335 shares of common stock, which may be deemed to be beneficially owned by Mr. Mitsakos as the sole owner, Chairman and CEO of Arcadia Holdings, Inc., the owner of such shares, (h) 219,335 shares of common stock issuable upon exercise by Arcadia Holdings, Inc. of warrants that are presently exercisable, at an exercise price of \$0.625 per share, and which may be deemed to be beneficially owned by Mr. Mitsakos, (i) 1,201,242 shares of common stock issued in the Holdings Merger to Arcadia Holdings, Inc., which Mr. Mitsakos may be deemed to beneficially own as the Chairman and CEO of Arcadia Holdings, Inc., and (j) 190,570 shares of common stock issued in the Holdings Merger.

- (4) The address of Mr. George W. Bickerstaff, III is c/o Cardax, Inc., 2800 Woodlawn Drive, Honolulu, Hawaii 96822. Mr. Bickerstaff is a member of our Board of Directors.
- (5) Represents 427,310 shares of common stock.
- (6) The address of Dr. Terence A. Kelly is c/o Cardax, Inc., 2800 Woodlawn Drive, Honolulu, Hawaii 96822. Dr. Kelly is a member of our Board of Directors.
- (7) Represents 411,163 shares of common stock.
- (8) The address of Mr. David G. Watumull is c/o Cardax, Inc., 2800 Woodlawn Drive, Honolulu, Hawaii 96822. Mr. David G. Watumull is our President, CEO, and a member of our Board of Directors.
- (9) Represents (a) 1,750,588 shares of common stock issuable upon exercise by Mr. David G. Watumull of options that are presently exercisable, at an exercise price of \$0.155 per share, (b) 4,941,845 shares of common stock issuable upon exercise by Mr. David G. Watumull of options that are presently exercisable, at an exercise price of \$0.625 per share, (c) 468,498 shares of common stock issuable upon exercise by Mr. David G. Watumull of options that are presently exercisable, at an exercise price of \$0.32 per share, (d) 390,686 shares of common stock issuable upon exercise by Mr. David G. Watumull of options that are presently exercisable, at an exercise price of \$0.20 per share, (e) 89,523 shares of common stock issuable upon exercise by Mr. David G. Watumull of options that are presently exercisable, at an exercise price of \$0.49 per share, (f) 137,675 shares of common stock issuable upon exercise by Mr. David G. Watumull of options that are presently exercisable, at an exercise price of \$0.27 per share, (g) 408,172 shares of common stock issued in the Holdings Merger, which Mr. Watumull may be deemed to beneficially own as the Trustee of the David G. Watumull Revocable Living Trust, and (h) 50,992 shares of common stock issuable upon exercise of a certain warrant issued in the Holdings Merger at an exercise price of \$0.981 per share, which Mr. Watumull may be deemed to beneficially own as the Trustee of the David G. Watumull Revocable Living Trust.
- (10) The address of Mr. David M. Watumull is c/o Cardax, Inc., 2800 Woodlawn Drive, Honolulu, Hawaii 96822. Mr. David M. Watumull is our Vice President, Operations.
- (11) Represents (a) 45,058 shares of common stock issuable upon exercise by Mr. David M. Watumull of options that are presently exercisable, at an exercise price of \$0.155 per share, (b) 2,388,554 shares of common stock issuable upon exercise by Mr. David M. Watumull of options that are presently exercisable, at an exercise price of \$0.625 per share, (c) 160,806 shares of common stock issuable upon exercise by Mr. David M. Watumull of options that are presently exercisable, at an exercise price of \$0.32 per share, (d) 284,917 shares of common stock issuable upon exercise by Mr. David M. Watumull of options that are presently exercisable, at an exercise price of \$0.20 per share, (e) 67,639 shares of common stock issuable upon exercise by Mr. David M. Watumull of options that are presently exercisable, at an exercise price of \$0.49 per share, and (f) 104,021 shares of common stock issuable upon exercise by Mr. David M. Watumull of options that are presently exercisable, at an exercise price of \$0.27 per share.
- (12) The address of Mr. John B. Russell is c/o Cardax, Inc., 2800 Woodlawn Drive, Honolulu, Hawaii 96822. Mr. Russell is our Chief Financial Officer.
- (13) Represents (a) 59,835 shares of common stock issuable upon exercise of options that are presently exercisable, at an exercise price of \$0.32 per share, which Mr. Russell may be deemed to beneficially own as the Managing Partner of JBR Business Solutions, LLC, (b) 62,424 shares of common stock issuable upon exercise of options that are presently exercisable, at an exercise price of \$0.20 per share, which Mr. Russell may be deemed to beneficially own as the Managing Partner of JBR Business Solutions, LLC, (c) 18,956 shares of common stock issuable upon exercise of options that are presently exercisable, at an exercise price of \$0.49 per share, which Mr. Russell may be deemed to beneficially own as the Managing Partner of JBR Business Solutions, LLC, and (d) 24,988 shares of common stock issuable upon exercise of options that are presently exercisable, at an exercise price of \$0.27 per share, which Mr. Russell may be deemed to beneficially own as the Managing Partner of JBR Business Solutions, LLC.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

Transactions with Related Persons

On June 30, 2015, we entered into an agreement with George W. Bickerstaff, III and Terence A. Kelly, Ph.D. that provided for the annual compensation of each independent director equal to \$100,000, payable quarterly in arrears in the form of a grant of shares of our common stock or non-qualified stock options to purchase shares of our common stock under the 2014 Plan. In addition, each independent director received a grant of 55,556 shares of Common Stock for compensation during June 2015. On September 30, 2015, each independent director received a grant of 73,529 shares of our common stock pursuant to the agreement. On December 31, 2015, each independent director received a grant of 100,000 shares of our common stock pursuant to the agreement. In addition, each of the directors has agreed, effective April 1, 2016, to suspend any additional equity compensation, until otherwise agreed by the Company.

On June 30, 2015, our compensation arrangement with JBR Business Solutions, LLC, under which John B. Russell serves as our Chief Financial Officer, was amended so that, effective after June 30, 2015, we had the right to pay up to 50% of any compensation due during any calendar quarter that was not paid in cash in the form of shares of our common stock or non-qualified stock options under the 2014 Plan. In addition, 50% of the amount of the unpaid cash compensation that accrued during the first and second quarters of 2015 was paid with non-qualified stock options under the 2014 Plan: 50% of the unpaid amount that accrued during the first quarter of 2015 or \$12,565 was paid by a non-qualified stock option to purchase 59,835 shares of our common stock at an exercise price of \$0.32 per share, and 50% of the unpaid amount that accrued during the second quarter of 2015 or \$8,115 was paid by a non-qualified stock option to purchase 62,424 shares of our common stock at an exercise price of \$0.20 per share. On September 30, 2015, 50% of the unpaid amount that accrued during the third quarter of 2015 or \$5,497 was paid by a non-qualified stock option to purchase 18,956 shares of our common stock at an exercise price of \$0.49 per share. On December 31, 2015, 50% of the unpaid amount that accrued during the fourth quarter of 2015 or \$5,497 was paid by a non-qualified stock option to purchase 24,988 shares of our common stock at an exercise price of \$0.27 per share. Mr. Russell is the Managing Partner of JBR Business Solutions, LLC. On March 28, 2016, Mr. Russell was furloughed and agreed to continue service as Chief Financial Officer for cash compensation equal to the minimum wage.

On December 30, 2015, we completed our merger with Holdings, our former principal stockholder. At closing, Holdings merged with and into us. There was not any cash consideration exchanged in the Holdings Merger. Upon the closing of the Holdings Merger, the stockholders of Holdings received an aggregate number of 31,597,574 shares of our common stock and warrants to purchase 1,402,426 shares of our common stock. The 33,000,000 restricted shares of our common stock held by Holdings were cancelled upon the closing of the Holdings Merger. Accordingly, there was not any change to our fully diluted capitalization due to the Holdings Merger. David G. Watumull and Nicholas Mitsakos were the only directors of Holdings upon the Holdings Merger. Each individual was also a director of us and a stockholder of Holdings. Each individual had a personal interest in the Holdings Merger, and received shares of our common stock in exchange for their equity interest in Holdings. An aggregate of 1,201,242 shares of our common stock were issued in the Holdings Merger to Arcadia Holdings, Inc., which Mr. Mitsakos may be deemed to beneficially own as the Chairman and CEO of Arcadia Holdings, Inc., and 190,570 shares of our common stock were issued in the Holdings Merger to Mr. Mitsakos. An aggregate of 408,172 shares of our common stock and a warrant to purchase 50,992 shares of our common stock at an exercise price equal to \$0.981 per share through December 31, 2018 were issued in the Holdings Merger to the David G. Watumull Revocable Living Trust, which Mr. Watumull may be deemed to beneficially own as the Trustee.

Director Independence

George W. Bickerstaff, III and Terence A. Kelly, Ph.D. are our independent directors. Because our common stock is not currently listed on a national securities exchange, we have used the definition of "independence" of The NASDAQ Stock Market to make this determination. NASDAQ Listing Rule 5605(a)(2) provides that an "independent director" is a person other than an officer or employee of the Company or any other individual having a relationship that, in the opinion of the Company's Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The NASDAQ listing rules provide that a director cannot be considered independent if:

- the director is, or at any time during the past three years was, an employee of the Company;
- the director or a family member of the director accepted any compensation from the Company in excess of \$120,000 during any period of 12 consecutive months within the three years preceding the independence determination (subject to certain exclusions, including, among other things, compensation for board or board committee service);
- a family member of the director is, or at any time during the past three years was, an executive officer of the Company;
- the director or a family member of the director is a partner in, controlling stockholder of, or an executive officer of an entity to which the Company made, or from which the Company received, payments in the current or any of the past three fiscal years that exceed 5% of the recipient's consolidated gross revenue for that year or \$200,000, whichever is greater (subject to certain exclusions);
- the director or a family member of the director is employed as an executive officer of an entity where, at any time during the past three years, any of the executive officers of the Company served on the compensation committee of such other entity; or
- the director or a family member of the director is a current partner of the Company's outside auditor, or at any time during the past three years was a partner or employee of the Company's outside auditor, and who worked on the Company's audit.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The table below sets forth the aggregate fees billed for fiscal years ended December 31, 2015 and 2014 for professional services rendered by the principal accountants for the audit of our annual consolidated financial statements and review of the consolidated financial statements included in our quarterly reports on Form 10-Q and services that are normally provided in connection with statutory and regulatory filings or engagements.

	<u>Fiscal Year Ended</u> <u>December 31, 2015</u>	<u>Fiscal Year Ended</u> <u>December 31, 2014</u>
Audit Fees ⁽¹⁾	\$ 67,500*	\$ 143,607*
Audit-Related Fees ⁽²⁾	\$ -	\$ -
Tax Fees ⁽³⁾	\$ -	\$ -
All Other Fees ⁽⁴⁾	\$ -	\$ -
Total	<u>\$ 67,500</u>	<u>\$ 143,607</u>

* The amounts of audit fees disclosed for our fiscal years ended December 31, 2015 and 2014 represent the aggregate audit fees billed during 2015 and 2014, respectively. The amount billed in 2015 includes fees incurred in connection with the audit of our financial statements for the fiscal year ended December 31, 2014 and the review of our interim financial statements in 2015. The amount billed in 2014 includes fees incurred in connection with the audit of our financial statements for the fiscal year ended December 31, 2013 and the review of our interim financial statements in 2014.

- (1) Audit fees consist of fees incurred for professional services rendered for the audit of our financial statements, for reviews of our interim financial statements included in our quarterly reports on Form 10-Q and for services that are normally provided in connection with statutory or regulatory filings or engagements.
- (2) Audit-related fees consist of fees billed for professional services that are reasonably related to the performance of the audit or review of our financial statements, but are not reported "Audit Fees."
- (3) Tax fees consist of fees billed for professional services relating to tax compliance, tax advice, and tax planning.
- (4) All other fees consist of fees billed for products and services provided by our principal accountants, other than for products and services reported above.

Audit Committee's Pre-Approval Policies

Our audit committee is responsible for, among other things, the selection, appointment, retention and dismissal of our independent auditors. Additionally, our audit committee pre-approves the retention of our independent auditors for any non-audit services, and the funding for payment of compensation to our independent auditors for both audit and non-audit services.

Audit Hours Incurred

Less than fifty percent of the hours expended on our principal accountant's engagement to audit our financial statements for the most recent fiscal year were attributed to work performed by persons other than our principal accountant's full-time, permanent employees.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) Financial Statements

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(b) Financial Statement Schedules

All consolidated financial statement schedules are included in the footnotes to the financial statements, or are inapplicable or otherwise not required.

(c) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
2.1 ⁽¹⁾	Agreement and Plan of Merger, dated as of November 27, 2013, by and among Koffee Korner Inc., Cardax Acquisition, Inc., Cardax Pharmaceuticals, Inc. and Cardax Pharma, Inc.
2.2 ⁽²⁾	First Amendment to the Agreement and Plan of Merger, dated as of January 10, 2014, by and among Koffee Korner Inc., Cardax Acquisition, Inc., Cardax Pharmaceuticals, Inc. and Cardax Pharma, Inc.
2.3 ⁽³⁾	Second Amendment to the Agreement and Plan of Merger, dated as of February 7, 2014, by and among Koffee Korner Inc., Cardax Acquisition, Inc., Cardax Pharmaceuticals, Inc. and Cardax Pharma, Inc.
2.4 ⁽⁴⁾	Amended and Restated Agreement and Plan of Merger, dated as of November 24, 2015 by and among Cardax Pharmaceuticals, Inc. and Cardax, Inc.
3.1 ⁽²⁾	Certificate of Incorporation, as amended, of Cardax, Inc.
3.2 ⁽²⁾	Amended and Restated Bylaws of Cardax, Inc.
4.1 ⁽³⁾	Form of specimen certificate representing Common Stock of Cardax, Inc.
4.2 ⁽³⁾	Form of Class A Warrant
4.3 ⁽³⁾	Form of Noteholder Warrant
4.4 ⁽³⁾	Form of Placement Agent Warrant
4.5 ⁽³⁾	Form of Financial Consultant Warrant
4.6 ⁽³⁾	Form of Warrant issued to JLS Ventures, LLC
10.1 ⁽²⁾	Cardax, Inc. 2014 Equity Compensation Plan
10.2 ⁽³⁾	Form of Stock Option Agreement under the 2014 Equity Compensation Plan
10.3 ⁽³⁾	Form of Notice of Stock Option Grant under the 2014 Equity Compensation Plan
10.4 ⁽³⁾	Form of Notice of Stock Option Grant In Substitution of Stock Option Grant under the Cardax Pharmaceuticals, Inc. 2006 Equity Compensation Plan

10.5⁽²⁾ Stock Purchase Agreement, dated as of January 10, 2014, by and among Koffee Korner Inc., Cardax Pharmaceuticals, Inc. and Cardax Pharma, Inc.

10.6 ⁽³⁾	Spin-off Agreement, dated as of February 7, 2014, between Koffee Korner Inc. and Nazneen D'Silva
10.7 ⁽³⁾	Senior Executive Employment Agreement, dated February 7, 2014, of David G. Watumull
10.8 ⁽³⁾	Senior Executive Employment Agreement, dated February 7, 2014, of David M. Watumull
10.9 ⁽³⁾	Senior Executive Employment Agreement, dated February 7, 2014, of Gilbert M. Rishton
10.10 ⁽³⁾	Senior Executive Employment Agreement, dated February 7, 2014, of Timothy J. King
10.11 ⁽³⁾	Agreement for Services as the Executive Chairman dated February 7, 2014, by and between Cardax, Inc. and Nicholas Mitsakos
10.12 ⁽⁵⁾	Form of Indemnification Agreement
10.13 ⁽⁵⁾	Form of Independent Board of Directors Agreement
10.14 ⁽⁶⁾	Joint Development and Supply Agreement effective on November 15, 2006, by and between BASF Aktiengesellschaft and Cardax Pharmaceuticals, Inc., as amended by Amendment No. 1 to Joint Development and Supply Agreement effective on April 15, 2007
10.15 ⁽⁷⁾	Collaboration Agreement, dated as of August 18, 2014, by and between Capsugel US, LLC and its affiliates and Cardax, Inc. and its affiliates
10.16 ⁽⁸⁾	Form of Registration Rights Agreement
10.17 ⁽⁸⁾	Form of Subscription Agreement
10.18 ⁽⁸⁾	Form of Class D Warrant
10.19 ⁽⁸⁾	Form of Class E Warrant
10.20 ⁽⁹⁾	Supplement to Agreement of the Executive Chairman
10.21 ⁽⁹⁾	Independent Directors' Compensation Agreement
10.22 ⁽⁹⁾	Supplement to Senior Executive Employment Agreement of David G. Watumull
10.23 ⁽⁹⁾	Payment Deferral and Acceptance Agreement of JBR Business Solutions, LLC
10.24 ⁽⁹⁾	Form of Payment Deferral and Acceptance Agreement
21.1 ⁽³⁾	Subsidiaries of Cardax, Inc.
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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- (1) Filed as an exhibit to the Current Report on Form 8-K of the Company filed November 29, 2013.
 - (2) Filed as an exhibit to the Current Report on Form 8-K of the Company filed January 14, 2014.
 - (3) Filed as an exhibit to the Current Report on Form 8-K of the Company filed February 10, 2014.
 - (4) Filed as an exhibit to the Current Report on Form 8-K of the Company filed November 24, 2015.
 - (5) Filed as an exhibit to the Amendment No. 1 to Registration Statement on Form S-1 of the Company dated September 2, 2014.
 - (6) Filed as an exhibit to the Current Report on Form 8-K/A of the Company dated April 16, 2014. Confidential treatment has been requested for this exhibit, and confidential portions have been filed separately with the SEC.
 - (7) Filed as an exhibit to the Amendment No. 3 to Registration Statement on Form S-1 of the Company dated November 26, 2014. Confidential treatment has been requested for this exhibit, and confidential portions have been filed separately with the SEC.
 - (8) Filed as an exhibit to the Current Report on Form 8-K of the Company filed March 9, 2015.
 - (9) Filed as an exhibit to the Current Report on Form 8-K of the Company filed July 7, 2015.

SIGNATURES

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

Dated: March 30, 2016

CARDAX, INC.

By: /s/ David G. Watumull

Name: David G. Watumull

Title: Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ David G. Watumull</u> David G. Watumull	President, Chief Executive Officer, and Director	March 30, 2016
<u>/s/ John B. Russell</u> John B. Russell	Chief Financial Officer and Treasurer	March 30, 2016
<u>/s/ Nicholas Mitsakos</u> Nicholas Mitsakos	Executive Chairman of the Board of Directors	March 30, 2016
<u>/s/ George W. Bickerstaff, III</u> George W. Bickerstaff, III	Director	March 30, 2016
<u>/s/ Terence A. Kelly, Ph.D.</u> Terence A. Kelly, Ph.D.	Director	March 30, 2016

Consolidated Financial Statements

Cardax, Inc., and Subsidiary

December 31, 2015 and 2014

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Cardax, Inc. and Subsidiary
Honolulu, Hawaii

We have audited the accompanying consolidated balance sheets of Cardax, Inc. and Subsidiary (the "Company") as of December 31, 2015 and 2014 and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cardax, Inc. and Subsidiary as of December 31, 2015 and 2014, and the results of its consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has sustained significant operating losses and needs to obtain additional financing to continue the development of their products. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KBL, LLP

New York, NY
March 30, 2016

Cardax, Inc., and Subsidiary
CONSOLIDATED BALANCE SHEETS

As of December 31,

	2015	2014
ASSETS		
CURRENT ASSETS		
Cash	\$ 323,410	\$ 35,696
Inventory	-	958,575
Deposits and other assets	87,715	92,829
Prepaid expenses	2,533	19,862
Total current assets	413,658	1,106,962
PROPERTY AND EQUIPMENT, net	13,923	20,611
INTANGIBLE ASSETS, net	424,497	419,518
TOTAL ASSETS	\$ 852,078	\$ 1,547,091
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accrued payroll and payroll related expenses	\$ 3,468,610	\$ 3,555,961
Accounts payable and accrued expenses	662,803	651,991
Fees payable to directors	418,546	418,546
Employee settlement	50,000	50,000
Other current liabilities	-	85,004
Total current liabilities	4,599,959	4,761,502
COMMITMENTS AND CONTINGENCIES	-	-
Total liabilities	4,599,959	4,761,502
STOCKHOLDERS' DEFICIT		
Common stock - \$0.001 par value; 400,000,000 shares authorized, 69,087,955 and 63,885,930 shares issued and outstanding as of December 31, 2015 and 2014, respectively	69,088	63,886
Additional paid-in-capital	50,333,188	46,908,249
Deferred compensation	-	(294,264)
Accumulated deficit	(54,150,157)	(49,892,282)
Total stockholders' deficit	(3,747,881)	(3,214,411)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$ 852,078	\$ 1,547,091

The accompanying notes are an integral part of these consolidated financial statements.

Cardax, Inc., and Subsidiary

CONSOLIDATED STATEMENTS OF OPERATIONS

For the years ended December 31,

	<u>2015</u>	<u>2014</u>
REVENUES	\$ -	\$ -
OPERATING EXPENSES:		
Stock based compensation	1,918,183	11,667,361
Selling, general, and administrative expenses	1,008,755	4,014,859
Inventory impairment	958,575	-
Research and development	491,829	1,160,771
Depreciation and amortization	23,758	38,972
Total operating expenses	<u>4,401,100</u>	<u>16,881,963</u>
Loss from operations	<u>(4,401,100)</u>	<u>(16,881,963)</u>
OTHER INCOME (EXPENSES):		
Interest expense	(2,334)	(118,780)
Interest income	2,355	3,692
Other income	48,204	-
Gain on sale of assets	95,000	2,426
Total other income (expenses)	<u>143,225</u>	<u>(112,662)</u>
Loss before provision for income taxes	<u>(4,257,875)</u>	<u>(16,994,625)</u>
PROVISION FOR INCOME TAXES	<u>-</u>	<u>-</u>
NET LOSS	<u>\$ (4,257,875)</u>	<u>\$ (16,994,625)</u>
NET LOSS PER SHARE		
Basic	\$ (0.06)	\$ (0.28)
Diluted	\$ (0.06)	\$ (0.28)
SHARES USED IN CALCULATION OF NET INCOME PER SHARE		
Basic	66,873,761	60,225,524
Diluted	66,873,761	60,225,524

The accompanying notes are an integral part of these consolidated financial statements.

Cardax, Inc., and Subsidiary

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT

For the years ended December 31, 2015 and 2014

	Common Stock		Preferred Series A		Preferred Series B		Additional Paid-In-Capital	Deferred Compensation	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2014 *	33,229,093	\$ 33,229	40,118,013	\$ 40,118	20,237,459	\$ 20,237	\$ 19,867,961	\$ -	\$ (32,897,657)	\$ (12,936,112)
Effect of reverse merger	5,548,404	5,548	(40,118,013)	(40,118)	(20,237,459)	(20,237)	54,807	-	-	-
Conversion of 2013 notes payable	14,446,777	14,447	-	-	-	-	9,014,813	-	-	9,029,260
Conversion of 2014 notes payable	3,353,437	3,353	-	-	-	-	2,092,554	-	-	2,095,907
Issuance of common stock	6,276,960	6,277	-	-	-	-	3,916,823	-	-	3,923,100
Common stock grants to independent directors	776,753	777	-	-	-	-	705,457	-	-	706,234
Deferred compensation	-	-	-	-	-	-	-	(294,264)	-	(294,264)
Stock option exercise	4,506	5	-	-	-	-	693	-	-	698
Common stock grants to consultant	250,000	250	-	-	-	-	87,250	-	-	87,500
Stock based compensation - warrants	-	-	-	-	-	-	5,250,540	-	-	5,250,540
Stock based compensation - options	-	-	-	-	-	-	5,917,351	-	-	5,917,351
Net loss	-	-	-	-	-	-	-	-	(16,994,625)	(16,994,625)
Balance at December 31, 2014	63,885,930	\$ 63,886	-	\$ -	-	\$ -	\$ 46,908,249	\$ (294,264)	\$ (49,892,282)	\$ (3,214,411)
Effect of merger with Cardax Pharmaceuticals, Inc.	(1,402,426)	(1,402)	-	-	-	-	1,402	-	-	-
Restricted stock issuances	6,020,725	6,021	-	-	-	-	1,800,201	-	-	1,806,222
Common stock grants to independent directors	458,170	458	-	-	-	-	116,209	-	-	116,667
Common stock grants to investor relations	100,000	100	-	-	-	-	44,900	-	-	45,000
Deferred compensation	-	-	-	-	-	-	-	294,264	-	294,264
Stock based compensation - options	-	-	-	-	-	-	1,409,592	-	-	1,409,592
Stock based compensation - warrants	-	-	-	-	-	-	48,700	-	-	48,700
Stock option exercise	25,556	25	-	-	-	-	3,935	-	-	3,960
Net loss	-	-	-	-	-	-	-	-	(4,257,875)	(4,257,875)
Balance at December 31, 2015	<u>69,087,955</u>	<u>\$ 69,088</u>	<u>-</u>	<u>\$ -</u>	<u>-</u>	<u>\$ -</u>	<u>\$ 50,333,188</u>	<u>\$ -</u>	<u>\$ (54,150,157)</u>	<u>\$ (3,747,881)</u>

* January 1, 2014 retroactively adjusted to reflect effects of the reverse acquisition transaction.

The accompanying notes are an integral part of these consolidated financial statements.

Cardax, Inc., and Subsidiary

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended December 31,

	<u>2015</u>	<u>2014</u>
Cash flows from operating activities:		
Net loss	\$ (4,257,875)	\$ (16,994,625)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	23,758	38,972
Stock based compensation	708,059	11,667,361
Amortization of debt discount	-	4,592
Gain on sale of assets	(95,000)	(2,426)
Inventory impairment	958,575	-
Changes in assets and liabilities:		
Deposits and other assets	5,114	1,391
Prepaid expenses	17,329	(5,482)
Inventory	-	28,099
Accrued payroll and payroll related expenses	1,122,773	(218,619)
Accounts payable and accrued expenses	10,808	(50,328)
Accrued interest	222	(101,553)
Fees payable to directors	-	(50,000)
Other current liabilities	-	(12,613)
Net cash used in operating activities	<u>(1,506,237)</u>	<u>(5,695,231)</u>
Cash flows from investing activities:		
Purchases of property and equipment	-	(1,633)
Proceeds from sale of property and equipment	10,000	87,430
Increase in patents	(22,049)	(26,670)
Net cash (used in) provided by investing activities	<u>(12,049)</u>	<u>59,127</u>
Cash flows from financing activities:		
Proceeds from the issuance of common stock	1,776,000	3,923,798
Proceeds from the issuances of notes payable	30,000	2,076,000
Repayment of principal on notes payable	-	(550,408)
Net cash provided by financing activities	<u>1,806,000</u>	<u>5,449,390</u>
NET INCREASE (DECREASE) IN CASH	287,714	(186,714)
Cash at the beginning of the year	<u>35,696</u>	<u>222,410</u>
Cash at the end of the year	<u>\$ 323,410</u>	<u>\$ 35,696</u>
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Conversion of notes payable and accrued interest into common stock	\$ 30,222	\$ 11,125,167
Conversion of accrued payroll and payroll related expenses into stock options	\$ 1,210,124	\$ -
Effect of merger with Cardax Pharmaceuticals, Inc.	\$ 1,402	\$ -
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	\$ 2,112	\$ 188,382
Cash paid for income taxes	\$ -	\$ -

The accompanying notes are an integral part of these consolidated financial statements.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – COMPANY BACKGROUND

Cardax Pharmaceuticals, Inc. (“Holdings”) was incorporated in the State of Delaware on March 23, 2006.

In May of 2006, Hawaii Biotech, Inc., contributed its anti-inflammatory, small molecule line of business into Holdings. Holdings issued (i) 9,447,100 shares of common stock of Holdings, (ii) 14,440,920 shares of Series A preferred stock of Holdings, (iii) 11,113,544 shares of Series B preferred stock of Holdings and (iv) 13,859,324 shares of Series C preferred stock of Holdings to Hawaii Biotech, Inc., in exchange for the assets and liabilities contributed to Holdings. The above shares were then distributed by Hawaii Biotech, Inc. to its shareholders. An additional 704,225 shares of Series C preferred stock were issued as part of the initial capitalization of Holdings. On January 30, 2007, all outstanding shares of Series A, B, and C preferred stock were converted into shares of Series A preferred stock.

Holdings was formed for the purpose of developing a platform of proprietary, exceptionally safe, small molecule compounds for large unmet medical needs where oxidative stress and inflammation play important causative roles. Holdings’ platform has application in arthritis, metabolic syndrome, liver disease, and cardiovascular disease, as well as macular degeneration and prostate disease. Holdings’ current primary focus is on the development of astaxanthin technologies. Astaxanthin is a naturally occurring marine compound that has robust anti-oxidant and anti-inflammatory activity.

In May of 2013, Holdings formed a 100% owned subsidiary company called Cardax Pharma, Inc. (“Pharma”). Pharma was formed to maintain Holdings’ operations going forward, leaving Holdings as an investment holding company.

On November 29, 2013, Holdings entered into a definitive merger agreement (“Merger Agreement”) with Koffee Korner Inc., a Delaware corporation (“Koffee Korner”) (OTCQB:KOFF), and its wholly owned subsidiary (“Koffee Sub”), pursuant to which, among other matters and subject to the conditions set forth in such Merger Agreement, Koffee Sub would merge with and into Pharma. In connection with such merger agreement and related agreements, upon the consummation of such merger, Pharma would become a wholly owned subsidiary of Koffee Korner and Koffee Korner would issue shares of its common stock to Holdings. At the effective time of such merger, Holdings would own a majority of the shares of the then issued and outstanding shares of common stock of Koffee Korner.

On February 7, 2014, Holdings completed its merger with Koffee Korner, which was renamed to Cardax, Inc. (the “Company”) (OTCQB:CDXI). Concurrent with the merger: (i) the Company received aggregate gross cash proceeds of \$3,923,100 in exchange for the issuance and sale of an aggregate 6,276,960 of shares of the Company’s common stock, together with five year warrants to purchase an aggregate of 6,276,960 shares of the Company’s common stock at \$0.625 per share, (ii) the notes issued on January 3, 2014, in the outstanding principal amount of \$2,076,000 and all accrued interest thereon, automatically converted into 3,353,437 shares of the Company’s common stock upon the reverse merger at \$0.625 per share, together with five year warrants to purchase 3,321,600 shares of common stock at \$0.625 per share, (iii) the notes issued in 2013, in the outstanding principal amount of \$8,489,036 and all accrued interest thereon, automatically converted into 14,446,777 shares of the Company’s common stock upon the reverse merger at \$0.625 per share, together with five year warrants to purchase 14,446,777 shares of common stock at \$0.625 per share, (iv) stock options to purchase 15,290,486 shares of Holdings common stock at \$0.07 per share were cancelled and substituted with stock options to purchase 6,889,555 shares of the Company’s common stock at \$0.155 per share, (v) additional stock options to purchase 20,867,266 shares of the Company’s common stock at \$0.625 per share were issued, and (vi) the notes issued in 2008 and 2009, in the outstanding principal amounts of \$55,000 and \$500,000, respectively, and all accrued interest thereon, were repaid in full. The assets and liabilities of Koffee Korner were distributed in accordance with the terms of a spin-off agreement on the closing date.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 1 – COMPANY BACKGROUND (continued)

The share exchange transaction was treated as a reverse acquisition, with Holdings and Pharma as the acquirers and Koffee Korner and Koffee Sub as the acquired parties. Unless the context suggests otherwise, when the Company refers to business and financial information for periods prior to the consummation of the reverse acquisition, the Company is referring to the business and financial information of Holdings and Pharma. Under accounting principles generally accepted in the United States of America (“U.S. GAAP”) guidance Accounting Standards Codification (“ASC”) No. 805-40, *Business Combinations – Reverse Acquisitions*, the Acquisition has been treated as a reverse acquisition with no adjustment to the historical book and tax basis of the Company’s assets and liabilities.

On August 28, 2014, the Company entered into an Agreement and Plan of Merger (the “Holdings Merger Agreement”) with its principal stockholder, Holdings, pursuant to which Holdings would merge with and into the Company (the “Holdings Merger”). On September 18, 2015, the Company filed a Form S-4 with the SEC in contemplation of the Holdings Merger. There would not be any cash consideration exchanged in the Holdings Merger. Upon the closing of the Holdings Merger, the stockholders of Holdings would receive an aggregate number of shares and warrants to purchase shares of the Company’s common stock equal to the aggregate number of shares of the Company’s common stock that were held by Holdings on the date of the closing of the Holdings Merger. The Company’s restricted shares of common stock held by Holdings would be cancelled upon the closing of the Holdings Merger. Accordingly, there would not be any change to the Company’s fully diluted capitalization due to the Holdings Merger.

On November 24, 2015, the Holdings Merger Agreement was amended and restated (the “Amended Holdings Merger Agreement”). Under the terms of Amended Holdings Merger Agreement, the shares of common stock, par value \$0.001 per share of Holdings and the shares of all other issued and outstanding capital stock of Holdings that by their terms were convertible or could otherwise be exchanged for shares of Holdings common stock, would be converted into and exchanged for the Company’s shares of Common Stock in a ratio of approximately 2.2:1. In addition, the Company would grant Holdings’ option and warrant holders warrants to purchase the Company’s warrants at the same stock conversion ratio. On November 24, 2015, the Company filed an amendment to the Form S-4 with the SEC and on December 29, 2015, the Form S-4 was declared effective by the SEC.

On December 30, 2015, the Company completed its merger with Holdings, pursuant to the Amended Holdings Merger Agreement. At closing, Holdings merged with and into the Company, with the Company surviving the Holdings Merger. Pursuant to the Amended Holdings Merger Agreement, there was not any cash consideration exchanged in the Holdings Merger. Upon the closing of the Holdings Merger, the stockholders of Holdings received an aggregate number of shares and warrants to purchase shares of Company common stock equal to the aggregate number of shares of Company common stock that were held by Holdings on the date of the closing of the Holdings Merger. The Company’s restricted shares of common stock held by Holdings were cancelled upon the closing of the Holdings Merger. Accordingly, there was not any change to the Company’s fully diluted capitalization due to the Holdings Merger.

Going concern matters

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements, the Company incurred a net loss of \$4,257,875 and \$16,994,625 for the years ended December 31, 2015 and 2014, respectively. The Company has incurred losses since inception resulting in an accumulated deficit of \$54,150,157 as of December 31, 2015, and has had negative cash flows from operating activities since inception. The Company anticipates further losses in the development of its business. As a result of these and other factors, the Company’s independent registered public accounting firm has determined there is substantial doubt about the Company’s ability to continue as a going concern.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 1 – COMPANY BACKGROUND (continued)

On March 28, 2016, the Company furloughed all of its employees and independent contractors indefinitely and arranged with its Chief Executive Officer, David G. Watumull; its Chief Financial Officer, John B. Russell; and its Vice President, Operations, David M. Watumull, to continue their services for cash compensation equal to the minimum wage. The Company continues to assess its commercial opportunities, which may include licensing its intellectual property or developing products with others, and may re-engage furloughed employees and contractors from time to time to the extent their services are required at cash compensation equal to the hourly minimum wage. In addition, each of the directors has agreed, effective April 1, 2016, to suspend any additional equity compensation, until otherwise agreed by the Company.

In addition to the \$1,806,000 raised during the year ended December 31, 2015, the Company plans to raise additional capital to carry out its business plan. The Company's ability to raise additional capital through future equity and debt securities issuances is unknown. Obtaining additional financing, the successful development of the Company's contemplated plan of operations, and its transition, ultimately, to profitable operations are necessary for the Company to continue operations. The ability to successfully resolve these factors raises substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements of the Company do not include any adjustments that may result from the outcome of these uncertainties.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The consolidated financial statements have been prepared in accordance with U.S. GAAP and include the accounts of Cardax, Inc., and its wholly owned subsidiary, Cardax Pharma, Inc., and its predecessor, Cardax Pharmaceuticals, Inc., which was merged with and into Cardax, Inc., on December 30, 2015. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and the accompanying notes. Estimates in these consolidated financial statements include asset valuations, estimates of future cash flows from and the economic useful lives of long-lived assets, valuations of stock compensation, certain accrued liabilities, income taxes and tax valuation allowances, and fair value estimates. Despite management's intention to establish accurate estimates and reasonable assumptions, actual results could differ materially from these estimates and assumptions.

Cash

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. The Company held no cash equivalents at December 31, 2015 and 2014.

The Company maintains cash deposit accounts at one financial institution. Accounts at this institution are insured by the Federal Deposit Insurance Corporation up to \$250,000. The Company's cash balance at times may exceed these limits. As of December 31, 2015, the Company had \$85,140 in excess of federally insured limits on deposit. As of December 31, 2014, the Company did not have any amounts in excess of federally insured limits on deposit.

Inventory

Inventory is stated at the lower of cost or market. Cost is determined using the average cost method. Market is defined as sales price less cost to dispose and a normal profit margin. Inventory costs include materials and third party costs.

The Company provides a reserve against inventory for known or expected inventory obsolescence. The reserve is determined by specific review of inventory items for product age and quality that may affect salability.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Property and equipment, net

Property and equipment are recorded at cost, less depreciation. Equipment under capital lease obligations and leasehold improvements are amortized on the straight-line method over the shorter period of the lease term or the estimated useful life of the equipment. Such amortization is included in depreciation and amortization in the consolidated financial statements. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets are as follows.

Furniture and office equipment	7 years
Research and development equipment	3 to 7 years
Information technology equipment	5 years
Software	3 years

Major additions and improvements are capitalized, and routine expenditures for repairs and maintenance are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts, and any resulting gain or loss is charged to income for the period.

Impairment of long-lived assets

In accordance with ASC 360 No., *Property, Plant, and Equipment*; the Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or group of assets, as appropriate, may not be recoverable.

When the sum of the undiscounted future net cash flows expected to result from the use and the eventual disposition is less than the carrying amounts, an impairment loss would be measured based on the discounted cash flows compared to the carrying amounts. There was no impairment charge recorded for the years ended December 31, 2015 and 2014.

Fair value measurements

U.S. GAAP establishes a framework for measuring fair value. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements).

The three levels of the fair value hierarchy are described below:

Level 1: Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the ability to access.

Level 2: Inputs to the valuation methodology include:

- Quoted prices for similar assets or liabilities in active markets;
- Quoted prices for identical or similar assets or liabilities in inactive markets;
- Inputs other than quoted prices that are observable for the asset or liability; and
- Inputs that are derived principally from or corroborated by observable market data by correlation or other means.

If the asset or liability has a specified (contractual) term, the Level 2 input must be observable for substantially the full term of the asset or liability.

Level 3: Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The asset's or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.

As of December 31, 2015 and 2014, there were no recurring fair value measurements of assets and liabilities subsequent to initial recognition.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Stock based compensation

The Company accounts for stock based compensation costs under the provisions of ASC No. 718, *Compensation—Stock Compensation*, which requires the measurement and recognition of compensation expense related to the fair value of stock based compensation awards that are ultimately expected to vest. Stock based compensation expense recognized includes the compensation cost for all stock based payments granted to employees, officers, directors, and consultants based on the grant date fair value estimated in accordance with the provisions of ASC No. 718. ASC No. 718 is also applied to awards modified, repurchased, or canceled during the periods reported.

Basic and diluted net income (loss) per share

Basic earnings per common share is calculated by dividing net loss for the year by the weighted average number of common shares outstanding during the year. Diluted earnings per common share is calculated by dividing net loss for the year by the sum of the weighted average number of common shares outstanding during the year plus the number of potentially dilutive common shares (“dilutive securities”) that were outstanding during the year. Dilutive securities include options granted pursuant to the Company’s stock option plans, and warrants issued to non-employees. Potentially dilutive securities are excluded from the computation of earnings per share in periods in which a net loss is reported, as their effect would be antidilutive.

Income taxes

The Company accounts for income taxes under an asset and liability approach. Deferred income taxes reflect the impact of temporary differences between assets and liabilities recognized for financial reporting purposes and the amounts recognized for income tax reporting purposes, net operating loss carry-forwards, and other tax credits measured by applying currently enacted tax laws. A valuation allowance is provided when necessary to reduce deferred tax assets to an amount that is more likely than not to be realized.

The Company determines whether a tax position is more likely than not to be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The Company uses a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained upon tax authority examination, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

The Company files income tax returns in the United States (“U.S.”) Federal and the States of Hawaii and California jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply.

The Company did not recognize any tax liabilities for income taxes associated with unrecognized tax benefits as of December 31, 2015 and 2014. It is the Company’s policy is to include interest and penalties related to unrecognized tax benefits, if any, within the provision for taxes in the statements of operations.

Advertising

Advertising costs are expensed as incurred and are included as an element of general and administrative costs in the accompanying statements of operations. There were no advertising expenses for the years ended December 31, 2015 and 2014.

Research and development

Research and development costs are expensed as incurred and consists primarily of salaries and wages of scientists and related personnel engaged in research and development activities, scientific consultations, manufacturing of product candidates, third-party research, laboratory supplies, rents associated with operating leased laboratory equipment, and scientific advisory boards. The focus of these costs is on the development of Astaxanthin technologies.

Reclassifications

The Company has made certain reclassifications to conform its prior periods’ data to the current presentation. These reclassifications had no effect on the reported results of operations or cash flows.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Recent accounting pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases*. The main provisions of ASU No. 2016-02 require management to recognize lease assets and lease liabilities for all leases. ASU 2016-02 retains a distinction between finance leases and operating leases. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous leases guidance. The result of retaining a distinction between finance leases and operating leases is that under the lessee accounting model, the effect of leases in the statement of comprehensive income and the statement of cash flows is largely unchanged from previous GAAP. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently assessing the impact of this ASU on the Company’s consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Income taxes*. The provisions of ASU No. 2015-17 simplify the presentation of deferred income taxes, the amendments in this ASU require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in this Update apply to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this Update. The amendments in this ASU are effective for the annual period ending after December 15, 2016, including interim periods within those fiscal years. The Company does not believe that the adoption of this update will have a significant impact to the Company’s consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory—Simplifying the Measurement of Inventory*. The provisions of ASU No. 2015-11 clarify measurement of inventory at the lower of cost or market and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amendments in this ASU are effective for the annual period ending after December 15, 2016, including interim periods within those fiscal years. The Company does not believe that the adoption of this update will have a significant impact to the Company’s consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern*. The provisions of ASU No. 2014-15 require management to assess an entity’s ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management’s plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management’s plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). The amendments in this ASU are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company is currently assessing the impact of this ASU on the Company’s consolidated financial statements.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material effect on the consolidated financial statements filed with this annual report.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 3 – INVENTORY

Inventory consists of the following as of:

	December 31, 2015	December 31, 2014
Processed materials	\$ -	\$ 958,575
Total inventories	<u>\$ -</u>	<u>\$ 958,575</u>

On January 5, 2016, the Company was informed by one of its production partners that there were certain technical issues which, together with other business and regulatory issues, materially impede the formulation of one of its potential products as a commercially viable product for the consumer health market. The Company, therefore, decided to suspend development of this product line. In evaluating this triggering event and the diminished utility of the materials used in the production of this potential commercial product, the Company considered the impact of FASB ASC No. 330, *Accounting for Inventory*, and recognized a loss on impairment of \$958,575 as of December 31, 2015.

At December 31, 2014, inventory in the amount of \$924,452 was stored at one of the Company's suppliers located in Germany, with the balance of the inventory maintained in the United States. During the year ended December 31, 2014, the Company utilized \$28,099 in Astaxanthin as part of commercial product research and development.

NOTE 4 – PROPERTY AND EQUIPMENT, net

Property and equipment, net, consists of the following as of:

	December 31, 2014	December 31, 2014
Information technology equipment	\$ 31,892	\$ 31,892
Furniture and office equipment	-	10,161
	31,892	42,053
Less accumulated depreciation	(17,969)	(21,442)
Total property and equipment, net	<u>\$ 13,923</u>	<u>\$ 20,611</u>

Depreciation expense was \$6,688 and \$7,063 for the years ended December 31, 2015 and 2014, respectively.

During the years ended December 31, 2015 and 2014, the Company wrote off \$10,161 and \$992,797, respectively, of fully depreciated property and equipment. There was no effect on the statement of operations for the years ended December 31, 2015 and 2014, respectively.

On December 16, 2014, the Company entered into an agreement to sell laboratory equipment with a net book value of \$0 for \$95,000. One payment of \$85,000 was received on December 26, 2014 with the balance being received on January 7, 2015. Final sale took place upon delivery of the equipment in February 2015.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 5 – INTANGIBLE ASSETS, net

Intangible assets, net, consists of the following as of:

	December 31, 2015	December 31, 2014
Patents	\$ 432,820	\$ 393,370
Less accumulated amortization	(217,342)	(200,272)
	<u>215,478</u>	<u>193,098</u>
Patents pending	209,019	226,420
Total intangible assets, net	<u>\$ 424,497</u>	<u>\$ 419,518</u>

Patents are amortized straight-line over a period of fifteen years. Amortization expense was \$17,070 and \$31,909, for the years ended December 31, 2015 and 2014, respectively.

The Company has capitalized costs for several patents that are still pending. In those instances, the Company has not recorded any amortization. The Company will commence amortization when these patents are approved.

The Company owns 21 issued patents, including 14 in the United States and 7 others in China, India, Japan, and Hong Kong. These patents will expire during the years of 2023 to 2028, subject to any patent term extensions of the individual patent. The Company has 5 foreign patent applications pending in Europe, Canada, and Brazil.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 6 – NOTE PAYABLE

On January 28, 2015, the Company received a short-term loan of \$30,000. The loan accrued interest at the rate of 3% per annum. Principal and interest were due on April 28, 2015. Interest accrued and expensed on this short-term loan was \$222 for the year ended December 31, 2015.

This note and accrued interest were converted on April 28, 2015 into securities of the Company at \$0.30 per unit. Each unit consisted of one share of restricted common stock (100,739 shares), two Class D warrants, each to purchase one share of restricted common stock at \$0.10 per share, which expire March 31, 2020, and one Class E warrant to purchase three-fourths of one share of restricted common stock at \$0.1667 per share, which expires March 31, 2020. “Most favored nation” rights are available to the purchaser of such units as described in the Subscription Agreement.

NOTE 7 – STOCKHOLDERS’ DEFICIT

Authorized shares - Holdings

On March 23, 2006, Holdings was authorized to issue 10,000 shares of common stock with a par value of \$0.001 per share. On May 5, 2006, the Articles of Incorporation were amended and restated. As part of this amendment, the number of authorized shares increased to 219,582,802 of which 127,000,000 were designated as common stock and the remaining 92,582,802 was designated as preferred stock. The 92,582,802 of preferred stock was allocated 14,440,920 to Series A, 11,113,544 Series B, 42,028,338 to Series C with 25,000,000 undesignated. Par value for all classes of stock was \$0.001.

On January 30, 2007, the Articles of Incorporation were amended and restated. As part of this amendment, the number of authorized shares increased to 245,673,568 of which 150,000,000 were designated as common stock and the remaining 95,673,568 was designated as preferred stock. The 95,673,568 of preferred stock was allocated 40,118,013 to Series A and 55,555,555 to Series B. As part of this amendment all outstanding shares of Series A, B, and C preferred stock on the date of amendment were converted into shares of Series A preferred stock. Par value for all classes of stock was \$0.001.

Dividends - Holdings

Subject to the rights of any series of Preferred Stock that may from time to time come into existence, the holders of Series A and Series B preferred stock were entitled to receive, when, as and if declared by the Board of Directors, out of funds legally available therefor, dividends at the rate of 8.5% of the original Series A Series and B issue prices, per annum, on each outstanding share of Series A and Series B preferred stock on a pari passu basis, payable in preference and priority to any payment of any dividend on common stock of the Company for such year. The right to such dividends on Preferred Stock were not cumulative, and no rights were to be accrued to the holders of Preferred Stock by reason of the fact that the Company may have failed to declare or pay dividends on Preferred Stock in any previous fiscal year of the Company, whether or not earnings of the Company were sufficient to pay such dividends. No dividend was to be paid on common stock in any year, other than dividends payable solely in common stock, until all dividends for such year had been declared and paid on preferred stock. No dividends were accrued or paid during 2015 and 2014.

Liquidation preference - Holdings

The holders of Series A and Series B preferred stock were entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of common stock by reason of their ownership of such stock, the amount of \$0.33, the original Series A issue price, and \$0.45, the original Series B issue price, (in each case adjusted for any stock dividends, combinations or splits with respect to such shares) for each share of Series A and Series B preferred stock, respectively, then held by them, and, in addition, an amount equal to all declared but unpaid dividends on Series A and Series B preferred stock, respectively, held by them.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 7 – STOCKHOLDERS' DEFICIT (continued)

Liquidation preference - Holdings (continued)

If the assets and funds thus distributed among the holders of Series A and Series B preferred stock were insufficient to permit the payment to such holders of full aforesaid preferential amounts, then, subject to the rights of series of preferred stock that may from time to time come into existence, the entire assets and funds of the Company legally available for distribution were to be distributed ratably among the holders of Series A and Series B preferred stock in the respective proportions which the aggregate preferential amount of all shares of Series A and Series B preferred stock then held by each such holder bears to the aggregate preferential amount of all shares of Series A and Series B preferred stock outstanding as of the date of the distribution upon the occurrence of such liquidation event.

After payment had been made to the holders of preferred stock of the full amounts to which they were to be entitled as aforesaid, the holders of Series A preferred stock, Series B preferred stock and common stock were to participate on a pro rata basis based on the number of Common Stock equivalent shares held by a holder in the distribution of all remaining assets of the Company legally available for distribution, with the outstanding shares of Series A and Series B preferred stock treated as though they had been converted into the appropriate number of shares of Common Stock.

Conversion rights - Holdings

Each share of Series A and Series B preferred stock were to be convertible, at the option of the holder thereof, at any time after the date of issuance of such share at the office of the Company or any transfer agent for such series of Series A or Series B preferred stock into such number of fully paid and non-assessable shares of common stock as is determined by dividing \$0.33 in the case of Series A preferred stock and \$0.45 in the case of Series B preferred stock, by the applicable Conversion Price, in effect on the date the certificate is surrendered for conversion. The price at which shares of Common Stock were to be deliverable upon conversion of Series A or Series B preferred stock were initially at \$0.33 per share with respect to shares of Series A preferred stock and \$0.45 per share with respect to shares of Series B preferred stock.

Voting rights - Holdings

The holder of each share of common stock issued and outstanding were to have one vote and the holder of each share of preferred stock were to be entitled to the number of votes equal to the number of shares of common stock into which such share of preferred stock would be converted.

Reverse acquisition accounting

On February 7, 2014, Koffee Sub and Pharma completed a reverse acquisition transaction (the "Acquisition"). Concurrent with this transaction: (i) the Company received aggregate gross cash proceeds of \$3,923,100 in exchange for the issuance and sale of an aggregate 6,276,960 of shares of the Company's common stock, together with five year warrants to purchase an aggregate of 6,276,960 shares of the Company's common stock at \$0.625 per share, (ii) the notes issued on January 3, 2014, in the outstanding principal amount of \$2,076,000 and all accrued interest thereon, automatically converted into 3,353,437 shares of the Company's common stock upon the reverse merger at \$0.625 per share, together with five year warrants to purchase 3,321,600 shares of common stock at \$0.625 per share, (iii) the notes issued in 2013, in the outstanding principal amount of \$8,489,036 and all accrued interest thereon, automatically converted into 14,446,777 shares of the Company's common stock upon the reverse merger at \$0.625 per share, together with five year warrants to purchase 14,446,777 shares of common stock at \$0.625 per share, (iv) stock options to purchase 15,290,486 shares of Holdings common stock at \$0.07 per share were cancelled and substituted with stock options to purchase 6,889,555 shares of the Company's common stock at \$0.155 per share, (v) additional stock options to purchase 20,867,266 shares of the Company's common stock at \$0.625 per share were issued, and (vi) the notes issued in 2008 and 2009, in the outstanding principal amounts of \$55,000 and \$500,000, respectively, and all accrued interest thereon, were repaid in full. The assets and liabilities of Koffee Korner were distributed in accordance with the terms of a spin-off agreement on the closing date.

The share exchange transaction was treated as a reverse acquisition, with Holdings and Pharma as the acquirers and Koffee Korner and Koffee Sub as the acquired parties. Unless the context suggests otherwise, when the Company refers to business and financial information for periods prior to the consummation of the reverse acquisition, the Company is referring to the business and financial information of Holdings and Pharma. Under U.S. GAAP guidance ASC 805-40, *Business Combinations – Reverse Acquisitions*, the Acquisition has been treated as a reverse acquisition with no adjustment to the historical book and tax basis of the Company's assets and liabilities.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 7 – STOCKHOLDERS' DEFICIT (continued)

Common stock – post reverse acquisition

After completion of the reverse merger on February 7, 2014, the Company Amended and Restated its Articles of Incorporation. Under these amendments, the Company is authorized to issue a total of four-hundred million shares of common stock and fifty million shares of preferred stock. Each common stock holder is entitled to one vote. Common stock holders have no conversion rights or liquidation preferences. None of the preferred stock was issued or outstanding at December 31, 2015. Under the terms of the Company's Amended and Restated Articles of Incorporation, the Board of Directors are authorized to determine or alter the rights, preferences, privileges, and restrictions of the Company's authorized but unissued shares of preferred stock.

Holdings Merger

On August 28, 2014, the Company entered into an Agreement and Plan of Merger (the "Holdings Merger Agreement") with its principal stockholder, Holdings, pursuant to which Holdings would merge with and into the Company (the "Holdings Merger"). On November 24, 2015, the Holdings Merger Agreement was amended and restated (the "Amended Holdings Merger Agreement"). Under the terms of the Amended Holdings Merger Agreement, the shares of common stock, par value \$0.001 per share of Holdings and the shares of all other issued and outstanding capital stock of Holdings that by their terms were convertible or could otherwise be exchanged for shares of Holdings common stock, would be converted into and exchanged for the Company's shares of Common Stock in a ratio of approximately 2.2:1. In addition, the Company would grant Holdings' option and warrant holders warrants to purchase the Company's warrants at the same stock conversion ratio.

On December 30, 2015, the Company completed its merger with Holdings, pursuant to the Amended Holdings Merger Agreement. At closing, Holdings merged with and into the Company, with the Company surviving the Holdings Merger. Pursuant to the Amended Holdings Merger Agreement, there was not any cash consideration exchanged in the Holdings Merger. Upon the closing of the Holdings Merger, the stockholders of Holdings received 31,597,574 shares and 1,402,426 warrants to purchase shares of common stock, which in aggregate was 33,000,000 shares. The Company's 33,000,000 restricted shares of common stock held by Holdings were cancelled upon the closing of the Holdings Merger. Accordingly, there was not any change to the Company's fully diluted capitalization due to the Holdings Merger.

Self-directed stock issuance

During the year ended December 31, 2015, the Company sold securities in a self-directed offering in the aggregate amount of \$1,806,222 at \$0.30 per unit, which included the conversion of the \$30,000 note payable and \$222 in accrued interest. Each unit consisted of one share of restricted common stock (6,020,725 shares), two Class D warrants, each to purchase one share of restricted common stock at \$0.10 per share, which expire March 31, 2020, and one Class E warrant to purchase three-fourths of one share of restricted common stock at \$0.1667 per share, which expires March 31, 2020. Warrants issued to date in this offering totaled 16,557,004. "Most favored nation" rights are available to the purchasers of such units as described in the Subscription Agreement.

NOTE 8 – STOCK GRANTS

Director stock grants

In 2014, the Company granted its independent directors an aggregate of 776,753 shares of restricted common stock in the Company. The total fair value of this stock on the date of grant was \$706,234. These shares were subject to a risk of forfeiture and vested quarterly in arrears commencing on June 1, 2014 and were fully vested at the end of one full year.

In 2015, the Company granted its independent directors an aggregate of 458,170 shares of restricted common stock in the Company. The total fair value of this stock on the date of grant was \$116,667. These shares were fully vested upon issuance.

The Company recognizes the expense related to these grants ratably over the requisite service period. Total stock compensation expense recognized as a result of these grants was \$410,931 and \$411,970 for the years ended December 31, 2015 and 2014, respectively.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 8 – STOCK GRANTS (continued)

Consultant stock issuance

During the years ended December 31, 2015 and 2014, the Company granted a consultant 100,000 and 250,000 shares of restricted common stock in the Company, respectively. Total expense recognized was \$45,000 and \$87,500 during the years ended December 31, 2015 and 2014, respectively, based on the total fair value of this stock on the date of grant.

NOTE 9 – STOCK OPTION PLANS

On May 15, 2006, the Company adopted the 2006 Stock Incentive Plan. Under this plan, the Company may issue shares of restricted stock, incentive stock options, or non-statutory stock options to employees, directors, and consultants. The aggregate number of shares which may be issued under this plan was 16,521,704, which was increased by 1,456,786 to 17,978,490 as part of the Series B Offering in 2007. This plan was terminated on February 7, 2014.

On February 7, 2014, the Company adopted the 2014 Equity Compensation Plan. Under this plan, the Company may issue options to purchase shares of common stock to employees, directors, advisors, and consultants. The aggregate number of shares that may be issued under this plan is 30,420,148. On April 16, 2015, the majority stockholder of the Company approved an increase in the Company's 2014 Equity Compensation Plan by 15 million shares.

Under the terms of the 2014 Equity Compensation Plan and the 2006 Stock Incentive Plan (collectively, the "Plans"), incentive stock options may be granted to employees at a price per share not less than 100% of the fair market value at date of grant. If the incentive stock option is granted to a 10% stockholder, then the purchase or exercise price per share shall not be less than 110% of the fair market value per share of common stock on the grant date. Non-statutory stock options and restricted stock may be granted to employees, directors, advisors, and consultants at a price per share, not less than 100% of the fair market value at date of grant. Options granted are exercisable, unless specified differently in the grant documents, over a default term of ten years from the date of grant and generally vest over a period of four years.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 9 – STOCK OPTION PLANS (continued)

A summary of stock option activity is as follows:

	Options	Weighted average exercise price	Weighted average remaining contractual term in years	Aggregate intrinsic value
Outstanding January 1, 2014	15,290,486	\$ 0.07	3.89	\$ 305,810
Exercisable January 1, 2014	15,290,486	\$ 0.07	3.89	\$ 305,810
Canceled	(15,290,486)			
Granted	27,756,821			
Exercised	(4,506)			
Forfeited	-			
Outstanding December 31, 2014	<u>27,752,315</u>	\$ 0.51	8.02	\$ 1,963,523
Exercisable December 31, 2014	<u>26,156,553</u>	\$ 0.50	7.95	\$ 1,962,239
Canceled	-			
Granted	6,456,890			
Exercised	(41,851)			
Forfeited	-			
Outstanding December 31, 2015	<u>34,167,354</u>	\$ 0.47	6.57	\$ 974,066
Exercisable December 31, 2015	<u>34,167,354</u>	\$ 0.47	6.57	\$ 974,066

The aggregate intrinsic value in the table above is before applicable income taxes and represents the excess amount over the exercise price option recipients would have received if all options had been exercised on December 31, 2015, based on a valuation of the Company's stock for that day.

A summary of the Company's non-vested options for the year ended December 31, 2015 and year ended December 31, 2014, are presented below:

Non-vested at January 1, 2014	-
Granted	27,756,821
Vested	(26,156,553)
Exercised	(4,506)
Forfeited	-
Non-vested at December 31, 2014	<u>1,595,762</u>
Granted	6,456,890
Vested	(8,010,801)
Exercised	(41,851)
Forfeited	-
Non-vested at December 31, 2015	<u><u>-</u></u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 9 – STOCK OPTION PLANS (continued)

Under ASC No. 718, the Company estimates the fair value of stock options granted on each grant date using the Black-Scholes option valuation model and recognizes an expense ratably over the requisite service period. The range of fair value assumptions related to options outstanding as of December 31, 2015 and 2014, were as follows:

	<u>December 31, 2015</u>	<u>December 31, 2014</u>
Dividend yield	0.0%	0.0%
Risk-free rate	0.12% - 1.47%	0.12% - 1.47%
Expected volatility	112% - 170%	112% - 170%
Expected term	1.1 - 5.5 years	1.1 - 5.5 years

The expected volatility was calculated based on the historical volatilities of publicly traded peer companies, determined by the Company. The risk free interest rate used was based on the U.S. Treasury constant maturity rate in effect at the time of grant for the expected term of the stock options to be valued. The expected dividend yield was zero, as the Company does not anticipate paying a dividend within the relevant time frame. Due to a lack of historical information needed to estimate the Company's expected term, it was estimated using the simplified method allowed under ASC No. 718. In calculating the number of options issued during the year ended December 31, 2015, the Company used assumptions comparable to December 31, 2014, with a 20-day weighted average stock price.

As part of the requirements of ASC No. 718, the Company is required to estimate potential forfeitures of stock grants and adjust stock based compensation expense accordingly. The estimate of forfeitures will be adjusted over the requisite service period to the extent that actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized in the period of change and will also impact the amount of stock based compensation expenses to be recognized in future periods.

The Company recognized \$1,413,552 and \$5,917,351 in stock based compensation expense related to options during the years ended December 31, 2015 and 2014, respectively. Of these amounts, \$1,210,124 and \$0 were related to 6,456,890 options issued to employees, directors, and consultants in lieu of salaries, wages, and fees accrued for services during the years ended December 31, 2015 and 2014, respectively.

Option exercise

On October 26, 2015, the Company issued 25,556 shares of common stock in the Company to a consultant in connection with the cashless exercise of a stock option for 41,851 shares of common stock at \$0.155 per share with 16,295 shares of common stock withheld with an aggregate fair market value equal to the aggregate exercise price.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – WARRANTS

The following is a summary of the Company's warrant activity:

	Warrants	Weighted average exercise price	Weighted average remaining contractual term in years	Aggregate intrinsic value
Outstanding January 1, 2014	3,395,833	\$ 0.45	5.28	\$ -
Exercisable January 1, 2014	3,395,833	\$ 0.45	5.28	\$ -
Canceled	(3,395,833)			
Granted	28,435,782			
Exercised	-			
Forfeited	-			
Outstanding December 31, 2014	<u>28,435,782</u>	\$ 0.64	4.07	\$ -
Exercisable December 31, 2014	<u>28,435,782</u>	\$ 0.64	4.07	\$ -
Canceled	-			
Granted	18,009,430			
Exercised	-			
Forfeited	-			
Outstanding December 31, 2015	<u>46,445,212</u>	\$ 0.46	3.48	\$ 2,517,337
Exercisable December 31, 2015	<u>46,445,212</u>	\$ 0.46	3.48	\$ 2,517,337

Under ASC No. 718, the Company estimates the fair value of warrants granted on each grant date using the Black-Scholes option valuation model. The fair value of warrants issued with debt is recorded as a debt discount and amortized over the life of the debt. The range of fair value assumptions related to warrants outstanding as of December 31, 2015 and 2014, were as follows:

	December 31, 2015	December 31, 2014
Dividend yield	0.0%	0.0%
Risk-free rate	0.12% - 0.86%	0.12% - 0.66%
Expected volatility	102% - 159%	112% - 159%
Expected term	1.0 - 2.5 years	1.0 - 2.5 years

The expected volatility was calculated based on the historical volatilities of publicly traded peer companies, determined by the Company. The risk free interest rate used was based on the U.S. Treasury constant maturity rate in effect at the time of grant for the expected term of the warrants to be valued. The expected dividend yield was zero, as the Company does not anticipate paying a dividend within the relevant time frame. The expected warrant term is the life of the warrant.

The Company recognized \$48,700 and \$5,250,540 in stock based compensation expense related to warrants for the years ended December 31, 2015 and 2014, respectively.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 11 – RELATED PARTY TRANSACTIONS

Executive chairman agreement

As part of an executive chairman agreement, a director provided services to the Company. The Company incurred \$240,000, in consulting fees to this director for the year ended December 31, 2014.

This agreement was amended on April 1, 2015. Under the terms of this amendment, this director receives \$37,500 in equity instruments issued quarterly in arrears as compensation. During the year ended December 31, 2015, the director incurred \$177,115 in consulting fees of which \$9,231 was settled in cash with \$167,884 being settled in options to purchase 851,963 shares of Company stock.

Amounts payable to this director was \$293,546 as of December 31, 2015 and 2014.

NOTE 12 – INCOME TAXES

The Company accounts for income taxes using the asset and liability method. Under this method, deferred income tax assets and liabilities are determined based upon the difference between the financial statement carrying amounts and the tax basis of assets and liabilities and are measured using the enacted tax rate expected to apply to taxable income in the years in which the differences are expected to be reversed.

The income tax provision (benefit) is composed of the following at December 31:

	2015			2014		
	Federal	State	Total	Federal	State	Total
Current	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Deferred	-	-	-	-	-	-
			\$ -			\$ -

The following table presents a reconciliation of the statutory Federal rate and the Company's effective tax rate for the years ended December 31:

	2015	2014
Tax provision (benefit) at Federal statutory rate	(34.00)%	(34.00)%
Accrued compensation	(0.70)%	(0.54)%
Accrued interest expense	(0.00)%	(1.31)%
Stock based compensation	15.32%	23.34%
Depreciation and amortization	0.22%	(0.08)%
Other	0.06%	0.10%
Change in valuation allowance	19.10%	12.49%
Effective tax rate	0.00%	0.00%

The effective tax rate for the years ended December 31, 2015 and 2014, differs from the statutory rate of 34% as a result of the state taxes (net of Federal benefit) and permanent differences.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 12 – INCOME TAXES (continued)

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The following table presents significant components of the Company's deferred tax assets and liabilities for the years ended December 31:

	2015	2014
Deferred tax assets:		
Net operating loss carryforwards	\$ 11,532,857	\$ 11,265,332
Stock based compensation	733,206	4,459,732
Accrued compensation	1,485,827	1,525,089
Credit carryforwards	106,856	124,525
Amortization	-	1,755
Gross deferred tax assets	<u>13,858,746</u>	<u>17,376,433</u>
Less valuation allowance	<u>(13,768,801)</u>	<u>(17,321,688)</u>
Net deferred tax assets	<u>89,945</u>	<u>54,745</u>
Deferred tax liabilities:		
Depreciation	(89,945)	(54,745)
Gain on sale of assets	-	-
Gross deferred tax liabilities	<u>(89,945)</u>	<u>(54,745)</u>
Net deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

As of December 31, 2015, the Company had Federal net operating loss carryforward of \$30,171,769. The net operating loss carryforward expires at various dates beginning in 2026 if not utilized. In addition, the Company had net operating losses for Hawaii income tax purposes of \$25,550,778 as of December 31, 2015, which expire at various dates beginning in 2026 if not utilized. These amounts differ from the Company's accumulated deficit due to permanent and temporary tax differences.

The Company's valuation allowance was primarily related to the operating losses. The valuation allowance is determined in accordance with the provisions of ASC No. 740, *Income Taxes*, which requires an assessment of both negative and positive evidence when measuring the need for a valuation allowance. Based on the available objective evidence and the Company's history of losses, management provides no assurance that the net deferred tax assets will be realized. As of December 31, 2015 and 2014, the Company has applied a valuation allowance against its deferred tax assets net of the expected income from the reversal of the deferred tax liabilities.

The Company is subject to taxation in the United States and two state jurisdictions. The preparation of tax returns requires management to interpret the applicable tax laws and regulations in effect in such jurisdictions, which could affect the amount of tax paid by the Company. Management, in consultation with its tax advisors, files its tax returns based on interpretations that are believed to be reasonable under the circumstances. The income tax returns, however, are subject to routine reviews by the various taxing authorities. As part of these reviews, a taxing authority may disagree with respect to the tax positions taken by management ("uncertain tax positions") and therefore may require the Company to pay additional taxes. Management evaluates the requirement for additional tax accruals, including interest and penalties, which the Company could incur as a result of the ultimate resolution of its uncertain tax positions. Management reviews and updates the accrual for uncertain tax positions as more definitive information becomes available from taxing authorities, completion of tax audits, expiration of statute of limitations, or upon occurrence of other events.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 12 – INCOME TAXES (continued)

As of December 31, 2015, there was no liability for income tax associated with unrecognized tax benefits. The Company recognizes accrued interest related to unrecognized tax benefits as well as any related penalties in interest income or expense in its consolidated statements of operations, which is consistent with the recognition of these items in prior reporting periods.

The federal and state income tax returns of the Company are subject to examination by the IRS and state taxing authorities, generally for three years after they were filed.

NOTE 13 – BASIC AND DILUTED NET INCOME (LOSS) PER SHARE

The following table sets forth the computation of the Company's basic and diluted net income (loss) per share for the nine-months ended:

	Year ended December 31, 2015		
	Net Loss (Numerator)	Shares (Denominator)	Per share amount
Basic loss per share	\$ (4,257,875)	66,873,761	\$ (0.06)
Effect of dilutive securities—Common stock options and warrants	-	-	-
Diluted loss per share	<u>\$ (4,257,875)</u>	<u>66,873,761</u>	<u>\$ (0.06)</u>
	Year ended December 31, 2014		
	Net Loss (Numerator)	Shares (Denominator)	Per share amount
Basic loss per share	\$ (16,994,625)	60,225,524	\$ (0.28)
Effect of dilutive securities—Common stock options and warrants	-	-	-
Diluted loss per share	<u>\$ (16,994,625)</u>	<u>60,225,524</u>	<u>\$ (0.28)</u>

The following outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share for the years presented because including them would have been antidilutive for the years ended:

	December 31, 2015	December 31, 2014
Common stock options	34,167,354	26,156,553
Common stock warrants	46,445,212	28,435,782
Total common stock equivalents	<u>80,612,566</u>	<u>54,592,335</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 14 – CONCENTRATION

The Company purchased all of its inventory from one vendor in Germany. Although, there were no purchases from this vendor during the two years ended December 31, 2015 and 2014, outstanding payables to this vendor were \$86,255 as of December 31, 2015, and 2014.

NOTE 15 – LEASES

Hawaii Research Center

The Company entered into a lease for laboratory and office space on May 9, 2006. This lease was amended on September 7, 2011, and October 30, 2012. This lease expired on October 31, 2014, after which the terms converted to month-to-month. The Company vacated the space in February 2015. Total rent expense under this agreement as amended was \$12,718 and \$56,856 for the years ended December 31, 2015 and 2014, respectively.

Manoa Innovation Center

The Company entered into an automatically renewable month-to-month lease for office space on August 13, 2010. Under the terms of this lease, the Company must provide a written notice 45 days prior to vacating the premises. Total rent expense under this agreement as amended was \$31,479 and \$28,169, for the years ended December 31, 2015 and 2014, respectively.

NOTE 16 – COMMITMENTS

Patent payable

As part of the formation of the Company, a patent license was transferred to the Company. The original license began in 2006. Under the terms of the license the Company agreed to pay \$10,000 per year through 2015 and royalties of 2% on any revenues resulting from the license. There were no revenues generated by this license during the years ended December 31, 2015 and 2014. The remaining obligation of \$20,000 as of December 31, 2015 and December 31, 2014, is recorded as a part of accounts payable on the consolidated balance sheets.

Employee settlement

As of December 31, 2015 and 2014, the Company owed a former employee a severance settlement payable in the amount of \$50,000 for accrued vacation benefits. As part of the severance settlement, a stock option previously granted to the former employee was fully vested and extended.

BASF agreement and license

In November 2006, the Company entered into a joint development and supply agreement with BASF SE (“BASF”). Under the agreement, the Company granted BASF an exclusive world-wide license to the Company’s rights related to the development and commercialization of Astaxanthin consumer health products; the Company retains all rights related to Astaxanthin pharmaceutical products. The Company is to receive specified royalties based on future net sales of such Astaxanthin consumer health products. No royalties were realized from this agreement during the years ended December 31, 2015 and 2014. The license does not prohibit the Company from purchasing Astaxanthin consumer health products from BASF for consumer health applications, similar to any third-party wholesale customer.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 16 – COMMITMENTS (continued)

Capsugel agreement

On August 18, 2014, the Company entered into a collaboration agreement with Capsugel US, LLC (“Capsugel”) for the joint commercial development of Astaxanthin products (“Capsugel Astaxanthin Products”) for the consumer health market that contain nature-identical synthetic Astaxanthin and use Capsugel’s proprietary formulation technology. The agreement provides for the parties to jointly administer activities under a product development plan that will include identifying at least one mutually acceptable third party marketer who will further develop, market and distribute Capsugel Astaxanthin Products. Capsugel will share revenues with the Company based on net sales of products that are developed under the collaboration. No revenues were realized from this agreement during the years ended December 31, 2015 and 2014. In January 2016, the Company suspended development of a Capsugel Astaxanthin Product, ASTX-1F, based on certain technical issues which, together with other business and regulatory issues, materially impeded the formulation of ASTX-1F as a commercially viable product for the consumer health market.

NOTE 17 – SUBSEQUENT EVENTS

The Company evaluated its December 31, 2015, consolidated financial statements for subsequent events through March 28, 2016, the date the consolidated financial statements were available to be issued and noted the following non-recognized events for disclosure.

On March 28, 2016, the Company furloughed all of its employees and independent contractors indefinitely and arranged with its Chief Executive Officer, David G. Watumull; its Chief Financial Officer, John B. Russell; and its Vice President, Operations, David M. Watumull, to continue their services for cash compensation equal to the minimum wage. The Company continues to assess its commercial opportunities, which may include licensing its intellectual property or developing products with others, and may re-engage furloughed employees and contractors from time to time to the extent their services are required at cash compensation equal to the hourly minimum wage. In addition, each of the directors has agreed, effective April 1, 2016, to suspend any additional equity compensation, until otherwise agreed by the Company.

**Supplemental Information to be Furnished With Reports Filed Pursuant to Section 15(d) of the Exchange Act by Registrants
Which Have Not Registered Securities Pursuant to Section 12 of the Exchange Act**

No annual report to security holders covering the Company's last fiscal year has been sent as of the date of this report. No proxy statement, form of proxy, or other proxy soliciting material relating to the Company's last fiscal year has been sent to any of the Company's security holders with respect to any annual or other meeting of security holders. If such report or proxy material is furnished to security holders subsequent to the filing of this Annual Report on Form 10-K, the Company will furnish copies of such material to the Commission at the time it is sent to security holders.

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

I, David G. Watumull, Chief Executive Officer, certify that:

1. I have reviewed this annual report on Form 10-K of Cardax, 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 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: March 30, 2016

/s/ David G. Watumull

David G. Watumull
Chief Executive Officer

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

I, John B. Russell, Chief Financial Officer, certify that:

1. I have reviewed this annual report on Form 10-K of Cardax, 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 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: March 30, 2016

/s/ John B. Russell

John B. Russell
Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)**

In connection with the Annual Report of Cardax, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report"), I, David G. Watumull, Chief Executive Officer, do hereby certify, to my knowledge:

(1) The Annual Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 30, 2016

By: /s/ David G. Watumull

David G. Watumull
Chief Executive Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Cardax, Inc. and will be retained by Cardax, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)**

In connection with the Annual Report of Cardax, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report"), I, John B. Russell, Chief Financial Officer, do hereby certify, to my knowledge:

(1) The Annual Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 30, 2016

By: /s/ John B. Russell

John B. Russell
Chief Financial Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Cardax, Inc. and will be retained by Cardax, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.
