

ChromaDex Corp.
Form 10-K
March 27, 2014

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 28, 2013

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

Commission file number 000-53290

CHROMADDEX CORPORATION
(Exact name of Registrant as specified in its Charter)

Delaware 26-2940963
(State or other jurisdiction of incorporation) (I.R.S. Employer Identification No.)

10005 Muirlands Blvd. Suite G, Irvine, California 92618
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (949) 419-0288

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

Title of each class	Name of Each Exchange on Which Registered
N/A	N/A

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$0.001 par value

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 Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes

Edgar Filing: ChromaDex Corp. - Form 10-K

No

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

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

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

Large accelerated filer

Accelerated Filer

Non-accelerated filer

Smaller Reporting Company

(Do not check if smaller reporting company)

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

As of June 29, 2013, the aggregate market value of the common stock held by non-affiliates of the Registrant was approximately \$47,056,942.

Number of shares of common stock of the registrant outstanding as of March 26, 2014: 106,149,101

DOCUMENTS INCORPORATED BY REFERENCE

None.

Table of Contents

TABLE OF CONTENTS

Item

PART I

	<u>Cautionary Notice Regarding Forward-Looking Statements</u>	
1.	<u>Business</u>	1
1A.	<u>Risk Factors</u>	13
2.	<u>Properties</u>	27
3.	<u>Legal Proceedings</u>	27
4.	<u>Mine Safety Disclosures</u>	27
	PART II	
5.	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	28
6.	<u>Selected Financial Data</u>	29
7.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	29
7A	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	37
8.	<u>Financial Statements and Supplementary Data</u>	38
9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	39
9A	<u>Controls and Procedures</u>	39
9B.	<u>Other Information</u>	41
	PART III	
10.	<u>Directors, Executive Officers and Corporate Governance</u>	42
11.	<u>Executive Compensation</u>	50
12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	60
13.	<u>Certain Relationships and Related Transactions, and Director Independence</u>	62
14.	<u>Principal Accounting Fees and Services</u>	63
	PART IV	
15.	<u>Exhibits, Financial Statement Schedules</u>	65
	<u>Signatures</u>	66

Table of Contents

PART I

CAUTIONARY NOTICE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K (the “Form 10-K”) contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934 and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect the current view about future events. When used in this Form 10-K the words “anticipate,” “believe,” “estimate,” “expect,” “future,” “intend,” “plan” or the negative of these terms and similar expressions relate to us or our management identify forward looking statements. Such statements, include, but are not limited to, statements contained in this Form 10-K relating to our business, business strategy, products and services we may offer in the future, sales and marketing strategy and capital outlook. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statement of historical fact nor guarantees of assurance of future performance. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward looking statements include, but are not limited to, a decline in general economic conditions nationally and internationally; decreased demand for our products and services; market acceptance of our products; the ability to protect our intellectual property rights; impact of any litigation or infringement actions brought against us; competition from other providers and products; risks in product development; inability to raise capital to fund continuing operations; changes in government regulation; the ability to complete customer transactions and capital raising transactions, and other factors (including the risks contained in Item 1A of this Form 10-K under the heading “Risk Factors”) relating to our industry, our operations and results of operations and any businesses that may be acquired by us. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we undertake no obligation to and do not intend to update any of the forward-looking statements to conform these statements to actual results.

Item 1. Business

Company Overview

The business of ChromaDex Corporation is conducted by our principal subsidiaries, ChromaDex, Inc., Chromadex Analytics, Inc. and Spherix Consulting, Inc. (“Spherix”). ChromaDex Corporation and its subsidiaries (collectively referred to herein as “ChromaDex” or the “Company” or, in the first person as “we” “us” and “our”) supplies phytochemical reference standards, which are small quantities of plant-based compounds typically used to research an array of potential attributes, and reference materials, related contract services, technical consulting and proprietary ingredients. We perform chemistry-based analytical services at our laboratory in Boulder, Colorado, typically in support of quality control or quality assurance activities within the dietary supplement industry. On December 3, 2012, we acquired Spherix, which provides scientific and regulatory consulting to the clients in the food, supplement and pharmaceutical industries to manage potential health and regulatory risks. In 2011, we launched the BluScience retail dietary supplement products containing one of the proprietary ingredients, pTeropure, which we also sell as an ingredient for incorporation into the products of other companies. However, on March 28, 2013, we entered into an asset purchase and sale agreement with NeutriSci International Inc. (“NeutriSci”) and consummated the sale of

the BluScience consumer product line to NeutriSci. For the fiscal years ended December 28, 2013 and December 29, 2012, our revenues were \$10,160,964 and \$11,610,494, respectively.

Table of Contents

We are a leading provider of research and quality-control products and services to the natural products industry. Customers worldwide in the dietary supplement, food and beverage, cosmetic and pharmaceutical industries use our products, which are small quantities of highly-characterized, research-grade, plant-based materials, to ensure the quality of their raw materials and finished products. Customers also use our analytical chemistry services to support their quality assurance activities, primarily to ensure the identity, potency and safety of their consumer products. We have conducted this core business since 1999.

We believe there is a growing need at both the manufacturing and government regulatory levels for reference standards, analytical methods and other quality assurance methods to ensure that products that contain plants, plant extracts and naturally occurring compounds distributed to consumers are safe. We further believe that this need is driven by the perception at the consumer level of a lack of adequate quality controls related to certain functional food or dietary supplement based products, as well as increased effort on the part of the Food and Drug Administration (“FDA”) to assure Good Manufacturing Practices (“GMP”).

Our core standards and contract service businesses provide us with the opportunity to become aware of the results from research and screening activities performed on thousands of potential natural product candidates. By selecting the most promising ingredients from this market-based screening model, which is grounded in primary research performed by leading universities and institutions, followed by selective investments in further research and development, new natural products-related intellectual property can be identified and brought to various markets with a much lower investment cost and an increased chance of success. The first of these proprietary compounds, pterostilbene, is marketed and sold under our brand name, pTeroPure. Pterostilbene is a polyphenol and a powerful antioxidant that shows promise in a range of health related issues. We have in-licensed patents pending related to the use of pterostilbene for a number of these benefits, and have filed additional patents related to additional benefits, such as a patent jointly filed with University of California at Irvine related to its effects on non-melanoma skin cancer. We have successfully conducted a clinical trial, together with the University of Mississippi, related to its blood pressure lowering effects. We expect to conduct additional clinical trials on this compound and we anticipate entering the dietary supplement, animal health and, if clinical results are favorable, the pharmaceutical market. We believe that we have opportunities in the skin care market and we will continue to investigate developing these opportunities internally or through third party partners.

Another one of these proprietary compounds is nicotinamide riboside (“NR”) for which our brand name is NIAGEN. NR is found naturally in trace amounts in milk and other foods and is the “no-flush” version of the B vitamin known as niacin. The potential beneficial effects of NR in humans include increased anti-aging, fatty acid oxidation, mitochondrial activity, resistance to negative consequences of high-fat diets, protection against oxidative stress, prevention of peripheral neuropathy and blocking muscle degeneration. Published research has shown that NR is a potent precursor to NAD+ in the mitochondria of animals. NAD+ is an important cellular co-factor for improvement of mitochondrial performance and energy metabolism. The Company has built a significant patent portfolio pertaining to NR by separately acquiring patent rights from Cornell University, Dartmouth College and Washington University. We anticipate conducting additional clinical trials on NR and other compounds in our pipeline to provide differentiation as we market these ingredients and support various health-related claims or obtain additional regulatory clearances.

With the addition of Spherix, we now provide our clients in the food, supplement and pharmaceutical industries with effective solutions to manage potential health and regulatory risks. Our science-based solutions are for both new and existing products that may be subject to product liability and/or exposed to changing scientific standards or public perceptions; literature evaluations; and design and assessment of pre-clinical and clinical safety testing. We specialize in regulatory submissions for food and dietary supplement ingredients. For our clients involved in drug development within the pharmaceutical industry, we provide similar services as well as risk-based strategies, including intellectual property data and compliance gap identification, due diligence assessments and investigational new drug writing. We

believe the addition of Spherix will complement and expand our leadership in reference standards and services business. By providing a more comprehensive suite of science-based and regulatory services, we will be able to more efficiently advance products in the dietary supplement, food and beverage, animal health, cosmetic and pharmaceutical markets.

-2-

Table of Contents

Company Background

ChromaDex, Inc. was originally formed as a California corporation on February 19, 2000. On April 23, 2003, ChromaDex Inc. acquired the research and development group of a competing natural product company called Napro Biotherapeutics located in Boulder, Colorado. The assets acquired in this transaction were placed in a newly-formed, wholly-owned subsidiary of ChromaDex named Chromadex Analytics, Inc., a Nevada corporation. On December 3, 2012, ChromaDex Inc. acquired a scientific and regulatory consulting company called Spherix Consulting Inc. located in the greater Washington D.C. area and Spherix Consulting Inc. became a wholly-owned subsidiary of ChromaDex, Inc.

Our Strategy

Our business strategy is to identify, acquire, reduce-to-practice, and commercialize innovative new natural products and technologies, with an initial industry focus on the dietary supplement, nutraceutical, food and beverage, functional food, animal health, pharmaceutical and skin care markets. We plan to utilize our experienced management team to commercialize these natural product technologies by advancing them through any required regulatory approval processes, selectively conducting clinical trials, arranging for reliable and cost-effective manufacturing, and ultimately either directly selling the products or licensing the intellectual property to third parties. We plan to conduct clinical trials to (a) reinforce the health benefits that may be associated with our ingredients in support of sales made into the dietary supplement and food and beverage markets, (b) potentially improve the quality or specificity of FDA approved claim we can make with respect to these health benefits, and (c) potentially lead us toward pharmaceutical applications for our ingredients.

• **Commercialization of intellectual property:** We believe that many of our products currently in development have the potential to spin off technologies that may themselves be independently capable of commercialization and becoming significant new revenue sources. We believe that new intellectual property can also be developed from our expansion into new markets.

• **Expansion and growth of the core business:** We intend to continue to expand our phytochemical standards offerings, which is the core of our business. Currently, we have approximately 4,500 defined standards. We expect to add about 500 new standards each year for the foreseeable future.

• **Expansion into new markets:** We are developing business in new domestic and international markets. These markets include both the domestic and international botanical drug market and the market for novel therapeutic botanicals from Asia, South America and Africa. We have also added what we believe to be new and innovative product offerings, including the screening of compound libraries and the offering of value-added raw materials.

• **Expansion through acquisitions:** We are a leader in the phytochemical standards market. We believe other smaller competitors are having difficulty expanding their revenue base and are prime candidates for acquisition by us. We believe that a long-term roll-up strategy could eventually lead to ChromaDex positioning itself as a provider of choice for phytochemical standards and libraries.

Overview of our Products and Services

We are headquartered in Irvine, California, and our analytical and research laboratory facility, Chromadex Analytics, is located in Boulder, Colorado. Chromadex Analytics operates a facility with 13,000 square feet of laboratory and office space. While we perform many of the contract services and research for our clients, Chromadex Analytics manufactures certain phytochemical reference standards, provides research and development, all analytical services and laboratory support for ChromaDex. Since 2003, we have invested in excess of \$2.5 million in laboratory

equipment, and we currently have personnel possessing over 150 years of combined pharmaceutical and natural products chemistry experience.

-3-

Table of Contents

We have recently acquired Spherix, located in the greater Washington D.C. area. Spherix provides its clients in the food, supplement and pharmaceutical industries with effective solutions to manage potential health and regulatory risks.

Current products and services provided are:

• **Dietary supplement and food ingredients.** We offer bulk raw materials for inclusion in dietary supplements, food, beverage and cosmetic products. This is an area where we are increasing our focus, as we believe we can secure and defend our market positions through patents and long-term manufacturing agreements with our customers and vendors.

• **Supply of reference standards, materials & kits.** Through our catalog, we supply a wide range of products necessary to conduct quality control of raw materials and consumer products. Reference standards and materials and the kits created from them are used for research and quality control in the dietary supplements, cosmetics, food and beverages, and pharmaceutical industries.

• **Supply of fine chemicals and phytochemicals.** As demand for new natural products and phytochemicals increases, we can scale up and supply our core products in the gram to kilogram scale for companies that require these products for research and new product development.

• **Contract services.** ChromaDex, through Chromadex Analytics, provides a wide range of contract services ranging from routine contract analysis for the production of dietary supplements, cosmetics, foods and other natural products to elaborate contract research for clients in these industries.

• **Consulting services.** We provide a comprehensive range of consulting services in the areas of regulatory support, new ingredient or product development, risk management and litigation support. With the addition of Spherix, we now can provide and are now offering product regulatory approval and scientific advisory services.

• **Process development.** Developing cost effective and efficient processes for manufacturing natural products can be very difficult and time consuming. We can assist customers in creating processes for cost-effective manufacturing of natural products, using “green chemistry.”

Products and services in development:

• **Nicotinamide riboside.** We are working to develop and conduct additional clinical trials to reinforce the health benefits associated with nicotinamide riboside. Nicotinamide riboside, a recently discovered vitamin found naturally in milk, is a more potent version of the more commonly known niacin (vitamin B3). Nicotinamide riboside has shown promise for improving cardiovascular health, glucose levels and cognitive function and has demonstrated evidence of anti-aging effects.

• **Pterostilbene and caffeine co-crystal.** We are working to develop and conduct additional clinical trials to reinforce the benefits of the co-crystal ingredient comprised of caffeine and pterostilbene. The first human study of this ingredient demonstrated that it delivers 30 percent more caffeine, stays in the blood stream longer, and is absorbed more slowly than ordinary caffeine. With this ingredient, formulators of energy products may have the ability to reduce the total amount of caffeine in their products by as much as 50% without sacrificing consumers’ expectations from such products.

• **Anthocyanin.** We are working to establish cost-effective methodologies for the efficient production of anthocyanins from genetically engineered bacteria. Anthocyanins are secondary plant metabolites that are mainly responsible for

the colors in plant tissues, primarily reds, purples and blues. They are non-toxic and have been observed to possess antioxidant, anticancer and anti-inflammatory activities, making them attractive candidates in the pharmaceutical, dietary supplement and food colorants industries.

Table of Contents

• **Process scale manufacturing.** We intend to invest in a pilot plant facility that has the capability of manufacturing at a process scale for products that have gone to market.

• **Phytochemical libraries.** We intend to continue investing in the development of natural product based libraries by continuing to create these libraries internally as well as through product licensing.

• **Plant extracts libraries.** We intend to continue our efforts to create an extensive library of plant extracts using our already extensive list of botanical reference materials.

• **Databases for cross-referencing phytochemicals.** We are working on building a database for cross referencing phytochemicals against an extensive list of plants, including links to references to ethnopharmacological, ethnobotanical, and biological activity, as well as clinical evidence.

• **Intellectual property.** We plan to utilize our expertise in natural products to license and develop new intellectual property that can be licensed to clients in our target industries.

Sales and Marketing Strategy

Our sales platform for the ingredients, core reference standards and analytical service business is based on a direct, inside technical sales model. We hire technical sales staff with appropriate scientific background in chemistry, biology, biochemistry or other related scientific fields. Our sales staff currently operates out of our Irvine, California office and performs sales duties by using combinations of telemarketing, e-mail, tradeshow and customer visits. It also has customer service responsibilities. We plan to add outside field sales representatives in the future as needed. All sales staff is compensated based on a uniform basic pay model based on salary and performance-based bonus.

Spherix, operating out of Rockville, Maryland, generates scientific and regulatory consulting revenue from an existing well-established list of Fortune 1000 customers and referrals. Our sales staff for the ingredients, reference standards and analytical service business in Irvine, California will also generate leads for Spherix.

USA and Canada:

For our ingredients, core reference standards and analytical service business, we employ the use of a direct mail marketing strategy (catalogs, brochures and flyers) in combination with a range of the following marketing activities to promote and sell our products and services:

- Tradeshows and conferences
- Monthly newsletters (via e-mail)
 - Internet
 - Website
- Advertising in trade publications
- Press releases

We intend to continue to use a direct marketing approach to promote our products and services to all markets that we target for direct sales.

Table of Contents

International:

For our core reference standards business, we use international distributors to market and sell to several foreign countries or markets. The use of distributors in some international markets has proven to be more effective than direct sales. Currently, we have exclusive distribution agreements in place with the following distributors for the following countries or regions:

- Europe (LGC Limited)
- South America (JMC, Inc.)
- Korea (Dong Myung Scientific Co.)
- India (LGC Promochem India Pvt. Ltd.)

We also use non-exclusive distributors for each of the following countries or groups of countries:

- Japan
- Australia and New Zealand
- China
- Indonesia, Malaysia, Singapore and Thailand
- Mexico

We may decide in the future to make non-exclusive distributors who show significant productivity in their designated market exclusive distributors in such markets.

Business Market

According to the Natural Marketing Institute, the Dietary Supplement, Functional Food and Beverage, and Natural Personal Care markets represent more than \$250 billion in annual worldwide sales. The quality control and assurance of some of the products in these markets are, as previously noted, largely “under regulated.” This scenario leads to the establishment of the basis of one of our business strategies: concentration on the overall content of products, as well as active/marker components, uniformity of production, and toxicology of products in these markets in ways similar to analysis by other companies focused in the pharmaceutical industry. There is an increasing demand for new products, ingredients and ideas for natural products. The pressure for new, innovative products, which are “natural” or “green” based, cuts across all markets including food, beverage, cosmetic and pharmaceutical.

While we believe that doctors and patients have become more receptive to the use of botanical and herbal-based and natural and dietary ingredients to prevent or treat illness and improve quality of life, the medical establishment has conditioned its acceptance on significantly improved demonstration of efficacy, safety and quality control comparable to that imposed on pharmaceuticals. Nevertheless, little is currently known about the constituents, active compounds and safety of many botanical and herbal natural ingredients and few qualified chemists and technology based companies exist to supply the information and products necessary to meet this burgeoning market need. Natural products are complex mixtures of many compounds, with significant variability arising from growing and extraction conditions. The following developments are some that highlight the need for standards control and quality assurance:

Table of Contents

- The FDA published its draft guidance for GMPs for dietary supplements on March 13, 2003. The final rule from this guidance was made effective in June 2007, and full compliance was required by June 2010; and

Regulatory agencies around the world have started to review the need for the regulation of herbal and natural supplements and are considering regulations that will include testing for the presence of toxic or adulterating compounds, drug/compound interactions and evidence that the products are biologically active for their intended use.

Business Model

We have taken advantage of both supply chain needs and regulatory requirements such as the GMPs for dietary supplements to build our core standards and analytical services businesses. We believe that we create value throughout the supply chain of the pharmaceutical, dietary supplements, functional foods and personal care markets. We do this by:

Combining the analytical methodology and characterization of materials with the technical support for the sale of reference materials by our clients;

- Helping companies to comply with new government regulations; and

Providing value-added solutions to every layer of the supply chain in order to increase the overall quality of products being produced.

In addition, the acquisition of Spherix has enabled us to be a premier provider of product regulatory approval and scientific advisory services. We can now provide our clients in the food, supplement and pharmaceutical industries with effective solutions to manage potential health and regulatory risks. Our science-based solutions are for both new and existing products that may be subject to product liability and/or exposed to changing scientific standards or public perceptions; literature evaluations; and design and assessment of pre-clinical and clinical safety testing. We specialize in regulatory submissions for food and dietary supplement ingredients. For our clients involved in drug development within the pharmaceutical industry, we provide similar services as well as risk-based strategies, including intellectual property data and compliance gap identification, due diligence assessments and investigational new drug writing. By providing a more comprehensive suite of science-based and regulatory services, we will be able to more efficiently advance products in the dietary supplement, food and beverage, animal health, cosmetic and pharmaceutical markets.

We believe we are now in a position to expand this aspect of our business and, more importantly, capitalize on additional opportunities in product development and commercialization of various kinds of intellectual property that we have largely discovered and acquired through the sales process associated with our standards and services businesses.

Our core standards and contract service businesses provide us with the opportunity to become aware of the results from research and screening activities performed on thousands of potential natural product candidates. By selecting the most promising ingredients from this market-based screening model, which is grounded in primary research performed by leading universities and institutions, followed by selective investments in further research and development, new natural products-related intellectual property can be identified and brought to various markets with a much lower investment cost and an increased chance of success. The first of these proprietary compounds, pterostilbene, is marketed and sold under our brand name, pTeroPure. Pterostilbene is a polyphenol and a powerful antioxidant that shows promise in a range of health related issues. We have in-licensed patents pending related to the use of pterostilbene for a number of these benefits, and have filed additional patents related to additional benefits, such as a patent jointly filed with University of California at Irvine related to its effects on non-melanoma skin cancer. We have successfully conducted a clinical trial, together with the University of Mississippi, related to its blood

pressure lowering effects. We expect to conduct additional clinical trials on this compound and we anticipate entering the dietary supplement, animal health and, if clinical results are favorable, possibly the pharmaceutical markets with it. We believe that we have opportunities in the skin care market and we will continue to investigate developing these opportunities internally or through third party partners.

-7-

Table of Contents

Another proprietary compound is nicotinamide riboside (“NR”), for which our brand name for this compound is NIAGEN. NR is found naturally in trace amounts in milk and other foods and is the “no-flush” version of the B vitamin known as niacin. The potential beneficial effects of NR in humans include increased anti-aging, fatty acid oxidation, mitochondrial activity, resistance to negative consequences of high-fat diets, protection against oxidative stress, prevention of peripheral neuropathy and blocking muscle degeneration. Published research has shown that NR is a potent precursor to NAD+ in the mitochondria of animals. NAD+ is an important cellular co-factor for improvement of mitochondrial performance and energy metabolism. The Company has built a significant patent portfolio pertaining to NR by separately acquiring patent rights from Cornell University, Dartmouth College and Washington University. We anticipate conducting additional clinical trials on NR and other compounds in our pipeline to provide differentiation as we market these ingredients and support various health-related claims or obtain additional regulatory clearances.

We continue to identify and in-license novel, proprietary compounds with significant potential health benefits. Among these next generation compounds are pterostilbene and caffeine co-crystal, which allows formulators of energy products to reduce the amount of caffeine in their products, and anthocyanins, which are compounds responsible for the dark pigment found in certain berries and flowers. Like pTeroPure and NIAGEN, these compounds also have potential in multiple markets.

Government Regulation

Some of our operations are subject to regulation by various United States federal agencies and similar state and international agencies, including the FDA, the Federal Trade Commission (“FTC”), the Department of Commerce, the Department of Transportation, the Department of Agriculture and other state and international agencies. These regulators govern a wide variety of production activities, from design and development to labeling, manufacturing, handling, selling and distributing of products. From time to time, federal, state and international legislation is enacted that may have the effect of materially increasing the cost of doing business or limiting or expanding our permissible activities. We cannot predict whether or when potential legislation or regulations will be enacted, and, if enacted, the effect of such legislation, regulation, implementation, or any implemented regulations or supervisory policies would have on our financial condition or results of operations. In addition, the outcome of any litigation, investigations or enforcement actions initiated by state or federal authorities could result in changes to our operations being necessary and in increased compliance costs.

FDA Regulation

Dietary supplements are subject to FDA regulations. For example, the FDA’s final rule on GMPs for dietary supplements published in June 2007 requires companies to evaluate products for identity, strength, purity and composition. These regulations in some cases, particularly for new ingredients, require a notification that must be submitted to the FDA along with evidence of safety. In addition, depending on the type of product, whether a dietary supplement, cosmetic, food, or pharmaceutical, the FDA, under the Food, Drug and Cosmetic Act, or FDCA, can regulate:

- product testing;