NATURAL ALTERNATIVES INTERNATIONAL INC Form 10-K September 17, 2010 Table of Contents

# **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 JUNE 30, 2010

000-15701

(Commission file number)

# NATURAL ALTERNATIVES INTERNATIONAL, INC.

(Exact name of registrant as specified in its charter)

Delaware (State of incorporation) 84-1007839 (IRS Employer Identification No.)

1185 Linda Vista Drive

San Marcos, California 92078 (Address of principal executive offices)

ia 92078 (760) 744-7340 ntive offices) (Registrant s telephone number) Securities registered pursuant to Section 12(b) of the Act:

Title of each class Common Stock, \$0.01 par value per share Name of exchange on which registered Nasdaq Global Market

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

#### None

Indicate by check mark if Natural Alternatives International, Inc. (NAI) is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933. "Yes x No

Indicate by check mark if NAI is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934. "Yes x No

Indicate by check mark whether NAI (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 NAI was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes  $\ddot{}$  No

Indicate by check mark whether NAI 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 NAI 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 NAI 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 NAI is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer " Accelerated filer " Non-accelerated filer " Smaller reporting company x

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

The aggregate market value of NAI s common stock held by non-affiliates of NAI as of the last business day of NAI s most recently completed second fiscal quarter (December 31, 2009) was approximately \$44,433,385 (based on the closing sale price of \$7.75 reported by Nasdaq on December 31, 2009). For this purpose, all of NAI s officers and directors and their affiliates were assumed to be affiliates of NAI.

As of September 17, 2010, 7,109,736 shares of NAI s common stock were outstanding, net of 180,941 treasury shares.

#### DOCUMENTS INCORPORATED BY REFERENCE

Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K incorporates by reference portions of NAI s definitive proxy statement for its Annual Meeting of Stockholders to be held December 3, 2010, to be filed on or before October 28, 2010.

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#### SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

Certain statements in this report, including information incorporated by reference, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934, and the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect current views about future events and financial performance based on certain assumptions. They include opinions, forecasts, intentions, plans, goals, projections, guidance, expectations, beliefs or other statements that are not statements of historical fact. Words such as may, could, will, should, would, expects, plans, believes, anticipates, intends, estimates, aŗ projects, or the negative or other variation of such words, and similar expressions may identify a statement as a forward-looking statement. Any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results, are forward-looking statements. Forward-looking statements in this report may include statements about:

future financial and operating results, including projections of net sales, revenue, income or loss, net income or loss per share, profit margins, expenditures, liquidity, and other financial items;

our ability to develop relationships with new customers and maintain or improve existing customer relationships;

future levels of our revenue concentration risk:

development of new products and marketing strategies;

the effect of the discontinuance of Dr. Cherry s television program and our ability to develop a new marketing plan for, and to sustain, our Pathway to Healing<sup>®</sup> product line;

distribution channels, product sales and performance, and timing of product shipments;

inventories and the adequacy and intended use of our facilities;

current or future customer orders;

the impact on our business and results of operations and variations in quarterly net sales from cost reduction programs, seasonal and other factors;

management s goals and plans for future operations;

our ability to improve operational efficiencies, manage costs and business risks and improve or maintain profitability;

growth, expansion, diversification, acquisition, divestment and consolidation strategies, the success of such strategies, and the benefits we believe can be derived from such strategies;

personnel;

the outcome of regulatory, tax and litigation matters;

our ability to operate within the standards set by the Food and Drug Administration s Good Manufacturing Practices;

sources and availability of raw materials;

operations outside the United States (U.S.);

the adequacy of reserves and allowances;

overall industry and market performance;

competition and competitive advantages resulting from our quality commitment;

current and future economic and political conditions;

the impact of accounting pronouncements; and

other assumptions described in this report underlying or relating to any forward-looking statements.

The forward-looking statements in this report speak only as of the date of this report and caution should be taken not to place undue reliance on any such forward-looking statements. Forward-looking statements are subject to certain events, risks, and uncertainties that may be outside of our control. When considering forward-looking statements, you should carefully review the risks, uncertainties and other cautionary statements in this report as they identify certain important factors that could cause actual results to differ materially from those expressed in or implied by the forward-looking statements. These factors include, among others, the risks described under Item 1A of Part I and elsewhere in this report, as well as in other reports and documents we file with the United States Securities and Exchange Commission (SEC).

PART I

ITEM 1. BUSINESS General

Our vision is to enrich the world through the best of nutrition.

We are a leading formulator, manufacturer and marketer of nutritional supplements and provide strategic partnering services to our customers. Our comprehensive partnership approach offers a wide range of innovative nutritional products and services to our clients including: scientific research, clinical studies, proprietary ingredients, customer-specific nutritional product formulation, product testing and evaluation, marketing management and support, packaging and delivery system design, regulatory review and international product registration assistance.

As our primary business activity, we provide private label contract manufacturing services to companies that market and distribute vitamins, minerals, herbs, and other nutritional supplements, as well as other health care products, to consumers both within and outside the United States. Additionally, we develop, manufacture and market our own branded products under the Pathway to Healing<sup>®</sup> product line, which is aimed at restoring, maintaining and improving health.

#### History

Originally founded in 1980, Natural Alternatives International, Inc. reorganized as a Delaware corporation in 1989. Our principal executive offices are located at 1185 Linda Vista Drive, San Marcos, California, 92078.

On January 22, 1999, Natural Alternatives International Europe S.A. (NAIE) was formed as our wholly owned subsidiary, based in Manno, Switzerland. In September 1999, NAIE opened its manufacturing facility and possesses manufacturing capability in encapsulation, powders, and tablets, finished goods packaging, quality control laboratory testing, warehousing, distribution and administration.

On December 5, 2005, we acquired Real Health Laboratories, Inc. (RHL), which primarily marketed branded nutritional supplements. On August 4, 2008, we sold certain assets related to RHL s catalog and internet business conducted under the name As We Charge to Miles Kimball Company for a cash purchase price of \$2.3 million. On July 31, 2009, we sold substantially all of the remaining assets of RHL related to its wholesale and direct-to-consumer business to PharmaCare US Inc. and PharmaCare Laboratories Pty Ltd. for a purchase price of \$500,000. We had the potential to receive up to an additional \$500,000 from the buyers as a conditional earn-out if the RHL business acquired by the buyers met or exceeded certain budgeted profitability criteria during the period August 1, 2009 through July 31, 2010. Effective as of February 12, 2010, based on the loss of one or more customers, the results of operation of the RHL business since the closing date of the sale, the anticipated results of operation of the RHL business through July 31, 2010, and the corresponding anticipated reduction in and/or elimination of the conditional earn-out amount, and in an effort to avoid the time and expense associated with the procedures required in connection with the earn-out, including, without limitation, the time and expense associated with the preparation of the required reports and a review of the books and records of PharmaCare US and PharmaCare Australia, we entered into an agreement with PharmaCare to eliminate the potential earn-out compensation. Following the sale of substantially all of the assets of RHL on July 31, 2009, we changed the name of RHL to Disposition Company, Inc. The financial information presented in this report has been reclassified to reflect the legacy RHL business as discontinued operations.

Unless the context requires otherwise, all references in this report to the Company, NAI, we, our, and us refer to Natural Alternatives International, Inc. and, as applicable, NAIE and our other wholly owned subsidiaries.

#### **Overview of our Facilities and Operations**

Our U.S.-based operations are located in San Marcos and Vista, California and include manufacturing and distribution, sales and marketing, in-house formulation, laboratory and other research and development services. Our manufacturing facilities were recertified on June 3, 2009 by the Therapeutic Goods Administration (TGA) of Australia after its audit of our Good Manufacturing Practices (GMP). TGA evaluates new therapeutic products, prepares standards, develops testing methods and conducts testing programs to ensure that products are high in quality, safe and effective. The TGA also conducts a range of assessment and monitoring activities including audits of the manufacturing practices of companies who export and sell products to Australia. TGA certification enables us to manufacture products for export into countries that have signed the Pharmaceutical Inspection Convention, which include most European countries as well as several Pacific Rim countries. TGA certifications are generally reviewed every eighteen months.

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Our California facilities also have been awarded GMP registration annually by NSF International (NSF) through the NSF Dietary Supplements Certification Program since October 2002 and received GMP for Sport NSF Certified registration on February 16, 2009. GMP requirements are regulatory standards and guidelines establishing necessary processes, procedures and documentation for manufacturers in an effort to assure the products produced by that manufacturer have the identity, strength, composition, quality and purity they are represented to possess.

NAIE also operates a manufacturing, warehousing, packaging and distribution facility in Manno, Switzerland. In January 2004, NAIE obtained a pharmaceutical license to process pharmaceuticals for packaging, importation, export and sale within Switzerland and other countries from the Swissmedic Authority of Bern, Switzerland. In March 2007, following the expansion of NAIE s manufacturing facilities to include powder filling capabilities, NAIE obtained an additional pharmaceutical license from the Swissmedic Authority certifying NAIE s expanded facilities conform to GMP. We believe these licenses and NAIE s manufacturing capabilities help strengthen our relationships with existing customers and can improve our ability to develop relationships with new customers. The licenses are valid until February 2014.

In addition to our operations in the United States and Switzerland, we have a part-time representative in Japan who provides a range of services to our customers currently present in or seeking to expand into the Japanese market and other markets in the Pacific Rim. These services include regulatory and marketing assistance along with guidance and support in adapting products to these markets.

#### **Business Strategy**

Our goals are to achieve long-term growth and profitability and to diversify our sales base. To accomplish these goals, we have sought and intend to continue to seek to:

leverage our state of the art, certified facilities to increase the value of the goods and services we provide to our highly valued private label contract manufacturing customers and assist in developing relationships with additional quality oriented customers;

provide strategic partnering services to our private label contract manufacturing customers, including, but not limited to, customized product formulation, clinical studies, regulatory assistance and product registration in foreign markets;

develop and grow our own line of branded products primarily through direct-to-consumer channels;

commercialize our patent estate through contract manufacturing, royalty and sub-license agreements and protect our proprietary rights; and

improve operational efficiencies and manage costs and business risks to improve profitability.

Overall, we believe there is an opportunity to enhance consumer confidence in the quality of our nutritional supplements and their adherence to label claims through the education provided by direct sales and direct-to-consumer marketing programs. We believe our GMP and TGA certified manufacturing operations, science based product formulations, peer-reviewed clinical studies and regulatory expertise provide us with a sustainable competitive advantage by providing our customers with a high degree of confidence in the products we manufacture.

While today s consumer may have access to a variety of information, we believe many consumers remain uneducated about nutrition and nutritional supplementation, uncertain about the relevance or reliability of the information they have or are confused about conflicting claims or information, which we believe creates a significant opportunity for the direct sales marketing channel. The direct sales marketing channel has proved, and we believe will continue to prove, to be a highly effective method for marketing high quality nutritional supplements as associates or other personalities educate consumers on the benefits of science based nutritional supplements. Our largest customers operate in the direct sales marketing channel. Thus, the majority of our business has been fueled primarily by the effectiveness of our customers in this marketing channel.

With the acquisition of RHL in 2005, we expanded our banded products segment to include the legacy RHL business, which included the internet and catalog business As We Change (AWC) and certain branded products primarily marketed through mass retail, with distribution to Food, Drug and Mass Market (FDM) retailers, as well as NAI s branded products primarily sold directly to consumers under the Pathway to Healing® product line. During the fourth quarter of fiscal 2008, however, we undertook a careful review of our branded products portfolio and operations and decided to narrow our branded products focus and developed and approved a plan to sell the legacy RHL business in an effort to enhance stockholder value, improve working capital and enable us to focus on our core contract manufacturing business. As of July 31, 2009, we had sold substantially all of the assets of RHL.

Following the completion of the sale of substantially all of the assets of RHL, our branded products segment consists primarily of the products sold under our Pathway to Healing<sup>®</sup> product line. During fiscal 2009, we revamped our website for this product line and increased our direct-to-consumer marketing and advertising efforts. During fiscal 2010, we further increased our marketing and advertising efforts with respect to our Pathway to Healing<sup>®</sup> product line and continue to evaluate alternative sales growth initiatives to support this branded business.

In the third quarter of fiscal 2009, we took steps to further commercialize our patent estate and entered into a sublicense agreement with Compound Solutions, Inc. (CSI) under which we agreed to grant a sublicense of certain of our patent and trademark rights to customers of CSI who purchase the raw ingredient beta-alanine under the CarnoSyn® trade name from CSI. The sublicense allows CSI s customers to manufacture, offer for sale and/or sell products incorporating, using or made in accordance with our patent and trademark rights. We receive a fee from CSI that varies based on the amount of net sales of beta-alanine sold by CSI, less CSI s costs and other agreed upon expenses.

We believe our comprehensive approach to customer service is unique within our industry. We believe this approach, together with our commitment to high quality, innovative products and investment in our continuing branded products, will provide the means to implement our strategies and achieve our goals. There can be no assurance, however, that we will successfully implement any of our business strategies or that we will increase or diversify our sales, develop and grow our branded products segment, successfully commercialize our patent estate or improve our overall financial results.

#### Products, Principal Markets and Methods of Distribution

Our primary business activity is to provide private label contract manufacturing services to companies that market and distribute vitamins, minerals, herbs, and other nutritional supplements, as well as other health care products, to consumers both within and outside the United States. Our private label contract manufacturing customers include companies that market nutritional supplements through direct sales marketing channels, direct response television and retail stores. We manufacture products in a variety of forms, including capsules, tablets, chewable wafers and powders to accommodate a variety of consumer preferences.

We provide strategic partnering services to our private label contract manufacturing customers, including the following:

customized product formulation;

clinical studies;

manufacturing;

marketing support;

international regulatory and label law compliance;

international product registration; and

packaging in multiple formats and labeling design.

Additionally, we develop, manufacture and market our own branded products and work with a nationally recognized physician to develop brand name products that reflect his individual approach to restoring, maintaining or improving health. These products are currently sold through print media and internet distribution channels.

For the last two fiscal years ended June 30, our net sales were derived from the following (in thousands):



Private Label Contract Manufacturing	\$ 63,346	96	\$ 71,242	93
Branded Products	2,207	3	2,677	3
Discontinued Operations (legacy RHL business)		1	2,913	4

Total Net Sales

\$65,876 100 \$76,832 100

#### **Research and Development**

We are committed to quality research and development. We focus on the development of new science based products and the improvement of existing products. We periodically test and validate our products to help ensure their stability, potency, efficacy and safety. We maintain quality control procedures to verify that our products comply with applicable specifications and standards established by the U. S. Food and Drug Administration (FDA) and other regulatory agencies. We also direct and participate in clinical research studies, often in collaboration with scientists and research institutions, to validate the benefits of a product and provide scientific support for product claims and marketing initiatives. We believe our commitment to research and development, as well as our facilities and strategic alliances with our suppliers and customers, allow us to effectively identify, develop and market high-quality and innovative products.

As part of the services we provide to our private label contract manufacturing customers, we may perform, but are not required to perform, certain research and development activities related to the development or improvement of their products. While our customers typically do not pay directly for this service, the cost of this service is included as a component of the price we charge to manufacture and deliver their products. Research and development costs, which include costs associated with international regulatory compliance services we provide to our customers, are expensed as incurred.

Our research and development expenses for the last two fiscal years ended June 30 were \$1.3 million for 2010 and \$1.2 million for 2009.

#### Sources and Availability of Raw Materials

We use raw materials in our operations including powders, excipients, empty capsules, and components for packaging and distributing our finished products. We conduct identity testing for all raw materials we purchase and, on a predetermined testing protocol basis, we evaluate raw materials to ensure their quality, purity and potency before we use them in our products. We typically buy raw materials in bulk from qualified vendors located both within and outside the United States. During fiscal 2010, Mannatech, Incorporated accounted for 11% of our total raw material purchases. We did not experience any significant shortages or difficulties obtaining adequate supplies of raw materials during fiscal 2010 and we do not anticipate any significant shortages or difficulties in the near term. During early fiscal 2009, however, we experienced increases in various product raw material costs, transportation costs and the cost of petroleum based raw materials and packaging supplies used in our business, which were associated with higher oil and fuel costs. We currently believe petroleum related raw material and product cost pricing pressures have stabilized and will remain relatively constant throughout fiscal 2011.

#### **Major Customers**

NSA International, Inc. (NSA) has been our largest customer over the past several years. During the fiscal year ended June 30, 2010, NSA accounted for approximately 52% of our net sales from continuing operations. We have a Manufacturing Agreement with NSA dated April 1, 2005, as amended. Under the terms of our agreement with NSA, we develop, manufacture, produce and package certain nutritional products for NSA based on monthly purchase orders submitted to us by NSA and provide certain consulting services, at such prices as are agreed upon from time to time. The agreement requires that NSA purchase at least 75% of NSA s monthly domestic requirements for certain of its products from us. The agreement expires on April 1, 2012, and may only be terminated in the event of a default under the agreement by either party. The agreement prohibits us from manufacturing or distributing any products that are substantially similar to the products we manufacture for NSA during the term of the agreement and for a period of three years thereafter.

Our second largest customer was Mannatech, Incorporated (Mannatech), which accounted for approximately 30% of our net sales from continuing operations during fiscal 2010. We have a Manufacturing Agreement with Mannatech and its affiliates dated April 22, 1998, as amended. Under the terms of our agreement with Mannatech, we manufacture, produce and bulk package certain nutritional products for Mannatech based on purchase orders submitted to us by Mannatech, at such prices as are agreed upon from time to time. The agreement automatically extends for successive one year periods unless terminated by either party in the event of a breach of the agreement with Mannatech and its affiliates dated November 19, 2004, under which we have the exclusive right to develop and manufacture certain products for Mannatech to be sold in Germany and Denmark. This agreement automatically extends for successive one year periods unless terminated by the other party for cause or in the event of a breach of the agreement by the other party for cause or in the event of a breach of the agreement by the other party for cause or in the event of a breach of the agreement by the other party or upon written notice prior to the expiration of the ther party or upon written notice prior to the expiration of the there exclusive right to develop and manufacture certain products for Mannatech to be sold in Germany and Denmark. This agreement automatically extends for successive one year periods unless terminated by either party for cause or in the event of a breach of the agreement by the other party or upon written notice prior to the expiration of the there party or upon written notice prior to the expiration of the then current term.

Both NSA International, Inc. and Mannatech, Incorporated are private label contract manufacturing customers. No other customer accounted for 10% or more of our net sales during fiscal 2010. We continue to focus on obtaining new private label contract manufacturing customers and growing our remaining branded products to reduce the risks associated with deriving a significant portion of our sales from a limited number of customers.

#### Competition

We compete with other manufacturers, distributors and marketers of vitamins, minerals, herbs, and other nutritional supplements both within and outside the United States. The nutritional supplement industry is highly fragmented and competition for the sale of nutritional supplements comes from many sources. These products are sold primarily through retailers (drug store chains, supermarkets, and mass market discount retailers), health and natural food stores, and direct sales channels (mail order, network marketing and e-marketing companies). The products we produce for our private label contract manufacturing customers may compete with our own branded products, although we believe such competition is limited.

We believe private label contract manufacturing competition in our industry is based on, among other things, customized services offered, product quality and safety, innovation, price and customer service. We believe we compete favorably with other companies because of our ability to provide comprehensive turnkey solutions for customers, our certified manufacturing operations and our commitment to quality and safety through our research and development activities.

Our future competitive position for both private label contract manufacturing and branded products will likely depend on, but not be limited to, the following:

the continued acceptance of our products by our customers and consumers;

our ability to continue to manufacture high quality products at competitive prices;

our ability to attract and retain qualified personnel;

the effect of any future governmental regulations on our products and business;

the results of, and publicity from, product safety and performance studies performed by governments and other research institutions;

the continued growth of the global nutrition industry; and

our ability to respond to changes within the industry and consumer demand, financially and otherwise. The nutritional supplement industry is highly competitive and we expect the level of competition to remain high over the near term. We do not believe it is possible to accurately estimate the total number or size of our competitors. The nutritional supplement industry has undergone consolidation in the recent past and we expect that trend to continue in the near term.

#### **Government Regulation**

Our business is subject to varying degrees of regulation by a number of government authorities in the U.S., including the FDA, the Federal Trade Commission (FTC), the Consumer Product Safety Commission, the U.S. Department of Agriculture, and the Environmental Protection Agency. Various agencies of the states and localities in which we operate and in which our products are sold also regulate our business, such as the California Department of Health Services, Food and Drug Branch. The areas of our business that these and other authorities regulate include, among others:

product claims and advertising;

product labels;

product ingredients; and

how we manufacture, package, distribute, import, export, sell and store our products.

The FDA, in particular, regulates the formulation, manufacturing, packaging, storage, labeling, promotion, distribution and sale of vitamin and other nutritional supplements in the U.S., while the FTC regulates marketing and advertising claims. In August 2007, a new rule issued by the FDA went into effect requiring companies that manufacture, package, label, distribute or hold nutritional supplements to meet certain GMPs to ensure such products are of the quality specified and are properly packaged and labeled. We are committed to meeting or exceeding the standards set by the FDA and believe we are currently operating within the FDA mandated GMPs.

The FDA also regulates the labeling and marketing of dietary supplements and nutritional products, including:

the identification of dietary supplements or nutritional products and their nutrition and ingredient labeling;

requirements related to the wording used for claims about nutrients, health claims, and statements of nutritional support;

labeling requirements for dietary supplements or nutritional products for which high potency and antioxidant claims are made;

notification procedures for statements on dietary supplements or nutritional products; and

premarket notification procedures for new dietary ingredients in nutritional supplements.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) revised the provisions of the Federal Food, Drug and Cosmetic Act concerning the composition and labeling of dietary supplements and defined dietary supplements to include vitamins, minerals, herbs, amino acids and other dietary substances used to supplement diets. DSHEA generally provides a regulatory framework to help ensure safe, quality dietary supplements and the dissemination of accurate information about such products. The FDA is generally prohibited from regulating active ingredients in dietary supplements as drugs unless product claims, such as claims that a product may heal, mitigate, cure or prevent an illness, disease or malady, trigger drug status.

In December 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act was passed, which further revised the provisions of the Federal Food, Drug and Cosmetic Act. Under the act, manufacturers, packers or distributors whose name appears on the product label of a dietary supplement or nonprescription drug are required to include contact information on the product label for consumers to use in reporting adverse events associated with the product s use and to notify the FDA of any serious adverse event report within 15 business days of receiving such report. Events reported to the FDA would not be considered an admission from a company that its product caused or contributed to the reported event. We are committed to meeting or exceeding the provisions of this act.

We are also subject to a variety of other regulations in the U.S., including those relating to bioterrorism, taxes, labor and employment, import and export, the environment and intellectual property.

Our operations outside the U.S. are similarly regulated by various agencies and entities in the countries in which we operate and in which our products are sold. The regulations of these countries may conflict with those in the U.S. and may vary from country to country. The sale of our products in certain European countries is subject to the rules and regulations of the European Union, which may be interpreted differently among the countries within the European Union. In markets outside the U.S., we may be required to obtain approvals, licenses or certifications from a country s ministry of health or comparable agency before we begin operations or the marketing of products in that country. Approvals or licenses may be conditioned on reformulation of our products for a particular market or may be unavailable for certain products or product ingredients. These regulations may limit our ability to enter certain markets outside the U.S.

#### **Intellectual Property**

*Trademarks*. We have developed and use registered trademarks in our business, particularly relating to corporate, brand and product names. We own 16 trademark registrations, including nine incontestable registrations, in the U.S. and have two trademark applications pending with the U.S. Patent and Trademark Office. Federal registration of a trademark affords the owner nationwide exclusive trademark rights in the registered mark and the ability to prevent others from using the same or similar marks. However, to the extent a common law user has made prior use of the mark in connection with similar goods or services in a particular geographic area, the nationwide rights conferred by federal registration would be subject to that geographic area.

We have one trademark registered with the Japanese Patent and Trademark Office and intend to register additional trademarks in foreign countries where our products are or may be sold in the future. We also claim common law ownership and protection of certain unregistered trademarks and service marks. Trademark rights are based on use of a mark. Common law use of a mark offers protection of a mark within the particular geographic area in which it is used. We believe our registered and unregistered trademarks constitute valuable assets, adding to the recognition of our products and services in the marketplace. These and other proprietary rights have been and will continue to be important in enabling us to compete.

*Trade Secrets.* We own certain intellectual property, including trade secrets we seek to protect, in part, through confidentiality agreements with employees and other parties. Although we regard our proprietary technology, trade secrets, trademarks and similar intellectual property as critical to our success, we rely on a combination of trade secrets, contract, patent, copyright and trademark law to establish and protect the rights in our products and technology. In addition, the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S.

*Patents and Patent Licenses*. Our business is not significantly dependent on our patents or patent licenses. We currently have exclusive worldwide rights to five U.S. patents, and each patent s corresponding foreign patents and applications, which include patents and applications in fifteen countries in Europe and Asia. Our rights continue until the expiration of the patents and we are required to make certain royalty payments to the original patent holders. All of these patents and patent rights relate to the ingredient known as beta-alanine marketed and sold under the CarnoSyn® trade name. We have sold this ingredient to customers for use in a limited market, and in March 2009 entered into an agreement to sublicense with Compound Solutions, Inc. (CSI) under which we agreed to grant a sublicense of certain of our patent rights to customers of CSI who purchase beta-alanine under the CaronSyn® trade name from CSI. The sublicense allows CSI s customers to manufacture, offer for sale and/or sell products incorporating, using or made in accordance with our patent rights. We receive a fee from CSI that varies based on the amount of net sales of beta-alanine sold by CSI less CSI s costs and other agreed upon expenses. Four of the patents expire in August 2017 and one patent expires in July 2026. Other patent applications, including those directed to controlled release formulations of beta-alanine and methods of treating certain muscle disorders and for improvement of muscle function using beta-alanine, are pending in the U.S. and in foreign jurisdictions. These patent applications have been assigned to NAI.

*Other Intellectual Property.* We have license agreements with Dr. Cherry and his ministries pursuant to which we have the right to use the names, likenesses, styles, personas and certain other intellectual property and attributes of Dr. Cherry to market and distribute nutritional and dietary supplements and related products and materials, including the Pathway to Healing<sup>®</sup> product line. The license agreements require the payment of certain royalties based on net sales. The licenses are in effect until December 31, 2011, and automatically extend for successive one

(1) year periods unless terminated by either party at least 120 days before the expiration of the then current term.

#### Employees

As of June 30, 2010, from continuing operations we employed 136 full-time employees in the U.S., two of whom held executive management positions. Of the remaining full-time employees, 24 were employed in research, laboratory and quality control, six in sales and marketing, and 104 in manufacturing and administration. From time to time we use temporary personnel to help us meet short-term operating requirements. These positions typically are in manufacturing and manufacturing support. As of June 30, 2010, we had 2 temporary personnel.

As of June 30, 2010, NAIE employed an additional 26 full-time employees. Most of these positions were in the areas of manufacturing and manufacturing support.

Our employees are not represented by a collective bargaining agreement and we have not experienced any work stoppages as a result of labor disputes. We believe our relationship with our employees is good.

#### Seasonality

Although we believe there is no material impact on our business or results of operations from seasonal factors, we have experienced and expect to continue to experience variations in quarterly net sales due to the timing of private label contract manufacturing orders.

#### Financial Information about Our Business Segments and Geographic Areas

Our operations are comprised of two reportable segments:

Private label contract manufacturing, in which we primarily provide manufacturing services to companies that market and distribute nutritional supplements and other health care products; and

Branded products, in which we market and distribute branded nutritional supplements through direct-to-consumer marketing programs, and under which we develop, manufacture and market our own products and work with a nationally recognized physician to develop brand name products that reflect his individual approach to restoring, maintaining or improving health. These products are currently sold through print media and the internet.

Our private label contract manufacturing products are sold both in the U.S. and in markets outside the U.S., including Europe, Australia and Asia. The primary market outside the U.S. is Europe. Our branded products are only sold in the U.S.

For additional financial information, including financial information about our business segment and geographic areas, please see the consolidated financial statements and accompanying notes to the consolidated financial statements included under Item 8 of this report.

Our activities in markets outside the U.S. are subject to political, economic and other risks in the countries in which our products are sold and in which we operate. For more information about these and other risks, please see Item 1A in this report.

#### ITEM 1A. RISK FACTORS

You should carefully review and consider the risks described below, as well as the other information in this report and in other reports and documents we file with the SEC when evaluating our business and future prospects. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties, not presently known to us, or that we currently see as immaterial, may also occur. If any of the following risks or any additional risks and uncertainties actually occur, our business, financial condition and results of operations could be seriously harmed. In that event, the market price of our common stock could decline and you could lose all or a portion of the value of your investment in our common stock. You should not draw any inference as to the magnitude of any particular risk from its position in the following discussion.

# Because we derive a significant portion of our revenues from a limited number of customers, our revenues would be adversely affected by the loss of a major customer or a significant change in its business, personnel or the timing or amount of its orders.

We have in the past and expect to continue to derive a significant portion of our revenues from a relatively limited number of customers. During the fiscal year ended June 30, 2010, sales to one customer, NSA International, Inc., were approximately 52% of our total net sales from continuing operations. Our second largest customer was Mannatech, Incorporated, which accounted for approximately 30% of our net sales from continuing operations during fiscal 2010. The loss of one of these customers or other major customers, a significant decrease in sales or the growth rate of sales to these customers, or a significant change in their business or personnel, would materially affect our financial condition and results of operations. Furthermore, the timing of our customers orders is impacted by, among others, their marketing programs, supply chain management, entry into new markets and new product introductions, all of which are outside of our control. All of these attributes have had and will have a significant impact on our business.

# Our future growth and stability depends, in part, on our ability to diversify our sales. Our efforts to establish new sales from existing customers and new customers and develop and grow our branded products could require significant initial investments, which may or may not result in higher sales and improved financial results.

Our business strategy depends in large part on our ability to develop new product sales from current and new customer relationships. These activities often require a significant up-front investment including, among others, customized formulations, regulatory compliance, product registrations, package design, product testing, pilot production runs, and the build up of initial inventory. In addition, we may incur increased marketing and advertising costs to the extent we seek to develop and grow our branded products. We may experience significant delays from the time we increase our operating expenses and make investments in inventory until the time we generate net sales from new products or customers, and it is possible that we may never generate any revenue from new products or customers after incurring such expenditures. If we incur significant expenses and investments in inventory that we are not able to recover, and we are not able to compensate for those expenses, our operating results could be adversely affected.

#### Our operating results will vary. We have experienced a decline in net sales and incurred losses in recent years and there is no guarantee that our sales will improve or that we will earn a profit in future years. Fluctuations in our operating results may adversely affect the share price of our common stock.

Our net sales from continuing operations declined during fiscal 2010 as compared to fiscal 2009 and there can be no assurance that our net sales will improve in the near term, or that we will earn a profit in any given year. We have experienced net losses in the past, including fiscal years 2009 and 2008, and may incur losses in the future. Our operating results will fluctuate from year to year and/or from quarter to quarter due to various factors including differences related to the timing of revenues and expenses for financial reporting purposes and other factors described in this report. At times, these fluctuations may be significant. We currently anticipate generating positive net income during the first quarter of fiscal 2011, although there is no assurance we will be able to do so. Fluctuations in our operating results may adversely affect the share price of our common stock.

# A significant or prolonged economic downturn, such as the one the global economy has recently experienced, could have, and recently has had, a material adverse effect on our results of operations.

Our results of operations are affected by the level of business activity of our customers and sublicensees, which in turn is affected by the level of consumer demand for their products. A significant or prolonged economic downturn may adversely affect the disposable income of many consumers and may lower demand for the products we produce for our private label contract manufacturing customers, as well as our branded products. During fiscal 2010, the decline in economic conditions in the U.S. and the various foreign markets in which our customers operate negatively impacted our customers businesses and our operations. A continued or further decline in consumer demand and the level of business activity of our customers due to economic conditions could have a material adverse effect on our revenues and profit margins.

Because our direct-to-consumer sales rely on the marketability of key personalities, the inability of a key personality to perform his or her role or the existence of negative publicity surrounding a key personality may adversely affect our revenues.

Direct-to-consumer products may be marketed with a key personality through a variety of distribution channels. The inability or failure of a key personality to fulfill his or her role, or the ineffectiveness of a key personality as a spokesperson for a product, a reduction in the exposure of a key personality due to the discontinuance of a marketing program or otherwise or negative publicity about a key personality may adversely affect the sales of our product associated with that personality and could affect the sale of other products. A decline in sales would negatively affect our results of operations and financial condition.

# Our industry is highly competitive and we may be unable to compete effectively. Increased competition could adversely affect our financial condition.

The market for our products is highly competitive. Many of our competitors are substantially larger and have greater financial resources and broader name recognition than we do. Our larger competitors may be able to devote greater resources to research and development, marketing and other activities that could provide them with a competitive advantage. Our market has relatively low entry barriers and is highly sensitive to the introduction of new products that may rapidly capture a significant market share. Increased competition could result in price reductions, reduced gross profit margins or loss of market share, any of which could have a material adverse effect on our financial condition and results of operations. There can be no assurance that we will be able to compete in this intensely competitive environment.

#### We may not be able to raise additional capital or obtain additional financing if needed.

Our cash from operations may not be sufficient to meet our working capital needs and/or to implement our business strategies. Additionally, there can be no assurance that our existing line of credit will be sufficient to meet our working capital needs. Furthermore, if we fail to maintain certain loan covenants we may no longer have access to the credit line. During fiscal 2009, we failed to meet certain of our loan covenants under our credit facility. While in each case our lender agreed to waive its default rights resulting from these covenant violations, there is no guarantee that the lender will continue to do so if we do not meet future covenant requirements. The credit line terminates in November 2011.

At any given time it may be difficult for companies to raise capital due to a variety of factors, some of which may be outside a company s control, including a tightening of credit markets, overall poor performance of stock markets, and/or an economic slowdown in the U.S. or other countries. Thus, there is no assurance we would be able to raise additional capital if needed. To the extent we do raise additional capital the ownership position of existing stockholders could be diluted. Similarly, there can be no assurance that additional financing will be available if needed or that it will be available on favorable terms. Under the terms of our credit facility, there are limits on our ability to create, incur or assume additional indebtedness without the approval of our lender.

Recent economic conditions have made it more difficult for companies to raise capital and obtain financing. Our inability to raise additional capital or to obtain additional financing if needed would negatively affect our ability to implement our business strategies and meet our goals. This, in turn, would adversely affect our financial condition and results of operations.

# The failure of our suppliers to supply quality materials in sufficient quantities, at a favorable price, and in a timely fashion could adversely affect the results of our operations.

We buy our raw materials from a limited number of suppliers. During fiscal 2010, approximately 25% of our total raw material purchases were from two suppliers. The loss of any of our major suppliers or of a supplier that provides any hard to obtain materials could adversely affect our business operations. Although we believe that we could establish alternate sources for most of our raw materials, any delay in locating and establishing relationships with other sources could result in product shortages, with a resulting loss of sales and customers. In certain situations we may be required to alter our products or to substitute different materials from alternative sources.

We rely solely on one supplier to process certain raw materials that we use in the product line of our largest customer. The loss of or unexpected interruption in this service would materially adversely affect our results of operations and financial condition.

A shortage of raw materials or an unexpected interruption of supply could also result in higher prices for those materials. During early fiscal 2009, we experienced increases in various product raw material costs, transportation costs and the cost of petroleum based raw materials and packaging supplies used in our business, which were associated with higher oil and fuel costs. We currently believe petroleum related raw material and product cost pricing pressures have stabilized and will remain relatively constant throughout fiscal 2011, although there is no assurance this will occur. Although we may be able to raise our prices in response to significant increases in the cost of raw materials, we may not be able to raise prices sufficiently or quickly enough to offset the negative effects of the cost increases on our results of operations or financial condition.

There can be no assurance that suppliers will provide the quality raw materials needed by us in the quantities requested or at a price we are willing to pay. Because we do not control the actual production of these raw materials, we are also subject to delays caused by interruption in production of materials based on conditions outside of our control, including weather, transportation interruptions, strikes and natural disasters or other catastrophic events.

In addition, under our sublicense agreement with CSI, we grant certain rights to customers of CSI who purchase the raw ingredient beta-alanine under the CarnoSyn® trade name from CSI and we receive a sublicense fee from CSI based on, among others, the amount of net sales of beta-alanine sold by CSI. CSI s ability to provide such raw ingredient to its customers could be negatively impacted by shortages, interruptions and similar risks described above, which could in turn adversely affect the amount of fees we receive from CSI.

#### Our business is subject to the effects of adverse publicity, which could negatively affect our sales and revenues.

Our business can be affected by adverse publicity or negative public perception about our industry, our competitors, our customers, or our business generally. This adverse publicity may include publicity about the nutritional supplements industry generally, the efficacy, safety and quality of nutritional supplements and other health care products or ingredients in general or our products or ingredients specifically, and regulatory investigations, regardless of whether these investigations involve us or the business practices or products of our competitors, or our customers. Any adverse publicity or negative public perception will likely have a material adverse effect on our business, financial condition and results of operations. Our business, financial condition and results of operations also could be adversely affected if any of our products or any similar products distributed by other companies are alleged to be or are proved to be harmful to consumers or to have unanticipated health consequences.

#### We could be exposed to product liability claims or other litigation, which may be costly and could materially adversely affect our operations.

We could face financial liability due to product liability claims if the use of our products results in significant loss or injury. Additionally, the manufacture and sale of our products involves the risk of injury to consumers from tampering by unauthorized third parties or product contamination. We could be exposed to future produ