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SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM ~~10-K~~ **ARLS**

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

For Fiscal Year ended June 30, 2004

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 0-14983

NUTRITION 21, INC.

(Exact Name of Registrant as Specified in its Charter)

New York  
(State or other jurisdiction of incorporation or organization)

11-2653613  
(I.R.S. Employer Identification No.)

4 Manhattanville Road, Purchase, New York 10577-2197  
(914) 701-4500

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

Securities registered pursuant to Section 12(g) of the Act:  
Common Stock (par value \$.005 per share)  
Title of Class

PROCESSED  
NOV 18 2004  
THOMSON  
FINANCIAL

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 twelve (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 ninety (90) days.  
Yes X No    

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the registrant's best 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. [X]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes     No X

Based on the last sale price as of December 31, 2003 (last business day of the Registrant's most recently completed second quarter), the aggregate market value of the voting stock held by non-affiliates of the registrant was \$21,537,342.

As of September 17, 2004, there were 37,991,988 shares of common stock outstanding.

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*Disclosures in this Form 10-K contain certain forward-looking statements, including without limitation, statements concerning the Company's operations, economic performance and financial condition. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate" and other similar expressions generally identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of their dates. These forward-looking statements are based largely on the Company's current expectations and are subject to a number of risks and uncertainties, including without limitation, changes in external market factors, changes in the Company's business or growth strategy or an inability to execute its strategy due to changes in its industry or the economy generally, the emergence of new or growing competitors, various other competitive factors and other risks and uncertainties indicated from time to time in the Company's filings with the Securities and Exchange Commission. Actual results could differ materially from the results referred to in the forward-looking statements. In light of these risks and uncertainties, there can be no assurance that the results referred to in the forward-looking statements contained in this Form 10-K will in fact occur. The Company makes no commitment to revise or update any forward looking statements in order to reflect events or circumstances after the date any such statement is made.*

## **PART I**

### **Item 1. OVERVIEW OF THE BUSINESS**

Nutrition 21 is a biosciences company dedicated to the research, development and commercialization of innovative chromium-based nutrition products for use in improving the structure or function of the body, and in the prevention and treatment of metabolic diseases such as diabetes, insulin resistance, obesity, depression and cardiovascular disease. Nutrition 21 holds 36 patents for nutrition products, 22 for chromium compounds and their uses. Nutrition 21's Chromax® chromium picolinate is a form of the essential mineral chromium developed by the USDA and licensed to the Company. It is used as an ingredient in many nutritional supplements.

The Company currently licenses chromium picolinate to vitamin and supplement manufacturers and marketers for use in human and animal nutrition products at doses typically between 50-400 mcg under its Chromax trademark. Finished products that incorporate chromium picolinate are marketed to enable consumers to meet their requirements for essential dietary chromium needs, and are regulated by the FDA under the Dietary Supplement Health and Education Act.

The function of insulin, the body's master metabolic hormone, is in part dependent on chromium that must be supplied through diet or supplementation. Recognizing that a number of the signs and symptoms of diabetes are shared in common with chromium deficiency, a 1999 Congressional mandate urged the National Institutes of Health's Office of Dietary Supplements (ODS) and the USDA to further evaluate the role of chromium in diabetes. An ODS November, 1999 Chromium and Diabetes Workshop Summary prioritized the research questions that had to

be resolved in order to evaluate chromium's potential role in preventing and/or mitigating diabetes management.

Since that time, Nutrition 21's core research and development program has followed the ODS research guidelines with the goal of further commercializing its chromium patent estate by expanding chromium use to therapeutic applications in diabetes and other health conditions linked to insulin resistance. According to the American Diabetes Association 18.2 million people suffer from diabetes; it is the sixth leading cause of death in the US and one its mostly costly health problems. Insulin resistance is thought to be a pre-cursor to diabetes and is estimated to affect one in five Americans according to the *Journal of American Dietetic Association*, February 2004.

In collaboration with both independent and sponsored academic researchers at leading international institutions and government agencies, the Company's research objectives are to:

- Firmly establish the safety of Chromax chromium picolinate
- Determine the mechanism of action of chromium picolinate in insulin mediated glucose metabolism
- Confirm a relationship between low chromium status and an increased risk of diabetes and other conditions linked to insulin resistance
- Use double-blind placebo-controlled trials to demonstrate the potential of its chromium product(s) to safely prevent, mitigate or treat diabetes
- Communicate the cost and health benefits of chromium-based supplements to secure approval of its product(s) for use as a first line therapy in diabetes management
- Identify other opportunities to expand the therapeutic use of its chromium technology

With successful research outcomes, the Company plans to publicize these findings to reposition its products and increase the demand for chromium picolinate use in vitamin and supplement formulas. Additionally, Chromax chromium picolinate has recently been affirmed as Generally Recognized as Safe (GRAS) for use in nutritional bars and beverages, and the Company is actively marketing its research findings to functional food manufacturers. This will be a new market for the Company's product.

In addition to its core chromium research program, the Company has recently begun to commercialize Diachrome, a newly patented combination of chromium picolinate and biotin, as a nutritional complement to medical treatment for people with type 2 diabetes. Diachrome will be sold as a finished consumer product, initially available through direct distribution to health care providers. Short term, small-scale, double-blind, placebo-controlled, peer-reviewed trials have already shown that Diachrome can significantly improve blood sugar and lipid profiles. The study outcomes compare favorably to drugs but without their side effects. Through a strategic alliance with XLHealth, a disease management company, the Company is currently conducting a large-scale trial to confirm these findings. With favorable Diachrome study outcomes, the Company hopes to have XLHealth incorporate Diachrome into its treatment protocol. This will be a key step in the Company's longer term program to secure government and health care approval of Diachrome as a reimbursed first line medical nutrition therapy for all US patients diagnosed with type 2 diabetes.

XLHealth, in partnership with Omnicare Inc., has been awarded funding by the Centers for Medicare and Medicaid Services (CMS) to conduct a demonstration project where they will provide disease management, counseling, monitoring and education to 10,000 Medicare beneficiaries who are chronically ill with severe diabetes, congestive heart failure and cardiovascular disease.

The Company holds patents for several other novel nutrition compounds and plans to expand its licensing program to include them once the Chromax expansion and Diachrome launch are underway.

## **History of the Company**

The Company is a New York corporation that was incorporated on June 29, 1983 as Applied Microbiology, Inc. Prior to 1995 the Company focused on the development and commercialization of antibacterial technologies for new drugs. The Company subsequently licensed these technologies to third parties. Beginning in 1995, the Company shifted its focus to developing and marketing nutrition products and ingredients. In 1997 the Company acquired a comprehensive chromium-based patent portfolio based on a picolinate form of chromium that was invented and researched by the United States Department of Agriculture. In 1999, the Company acquired the Lite Bites consumer product line from Optimum Lifestyles, Inc. In August of 2003, the Company discontinued its investment in the Lite Bites product line and recorded a \$4.4 million charge relating to the discontinuance.

## **The Company's Products and Proposed Products**

### The Company's Existing Ingredients Business

Since 1997, the Company's primary business has been to develop and market proprietary ingredients to the vitamin and supplement market for both human and animal applications. Today, Chromax® chromium picolinate is the Company's primary ingredients product.

The Company's ingredient customers distribute Chromax as a stand-alone chromium supplement either under the Chromax name under license from the Company, or under their own private labels. A license from the Company is required for all chromium picolinate products that are sold in the US for glucose control and its derivative benefits, including cholesterol control and improved body composition.

The calendar 2003 annual US retail market for stand-alone chromium mineral supplements is estimated to be \$106 million based on retail sales data provided by Nutrition Business Journal compared to \$85 million for calendar 2002. Based on SPINS and Information Resources, Inc. ("IRI") data, more than 80% of US chromium supplements are formulated with the Company's Chromax chromium picolinate, while the rest are manufactured using chloride, polynicotinate or other forms.

The Company derives additional revenues from the sale and licensing of Chromax to customers who incorporate it and other of the Company's ingredients into over 900 finished multi-ingredient products. These include vitamin/mineral formulas, weight loss and sports nutrition

supplements, baked goods, beverages and other products. These products are sold by the Company's customers under a variety of brands throughout the world through natural/health food stores, supermarkets, drug stores, and mass merchandisers, and also through direct sales and catalogue sales.

Chromax chromium picolinate is also used for managing the health of breeding sows and their offspring, where it has been shown to improve glucose control in gestating swine. Research outcomes include improved fertility, productivity and recovery for the sows, and stronger and more resilient offspring.

The Company's principal customers have entered into master license agreements with the Company that cover purchases that they decide to make from the Company from time to time. The Company has no long-term purchase or sale commitments with its customers. The master license grants to these customers a license under the Company's patents to sell chromium picolinate for the particular uses covered by the patents. The fee for this license is bundled on an unallocated basis with the price that the Company charges to its customers for products that the Company sells to them. See "Supply and Manufacturing" for information on a manufacturing agreement between the Company and the manufacturer of its principal products.

During each of the fiscal years ended June 30, 2004, 2003 and 2002, respectively, ingredient sales of chromium picolinate accounted for more than 83%, 74%, and 64% of the Company's total revenues. Sales of the Company's Lite-Bite products during these three fiscal years accounted for more than 4%, 8%, and 27% of the Company's total revenues. One customer, Prince Agri Products, Inc., accounted for 18%, 19%, and 13% of the Company's total revenues, respectively, in the Company's 2004, 2003 and 2002 fiscal years.

In marketing its Chromax chromium picolinate, the Company must continue to demonstrate the safety of this product. The following studies in the Company's opinion demonstrate that chromium picolinate is safe.

The United States Government, acting through the National Institutes of Health-National Toxicology Program ("NTP"), has independently evaluated the safety of chromium picolinate with government approved tests. In 2002, the NTP did not find any safety concerns with chromium picolinate, even at high doses.

In 2002 a group of experts consisting of Richard Anderson, Ph.D. (senior scientist, USDA chromium expert), Walter Glinsman, MD (former director from the FDA), and Joseph Borzelleca, Ph.D. (professor emeritus of pharmacology and toxicology from Virginia Commonwealth University) reviewed all existing studies of chromium picolinate and found no safety concerns.

In 1997 United States Department of Agriculture ("USDA") researchers published results of a high dose chromium picolinate study, concluding that chromium picolinate is safe.

However, several researchers have questioned the safety of chromium picolinate. In 1995 and 2002 a research group headed by Dianne Stearns, Ph.D. (University of Dartmouth College and Northern Arizona University) administered chromium picolinate in a laboratory to Chinese

hamster ovary cell lines, and in 2003 another research group headed by John Vincent, Ph.D. (University of Alabama) administered chromium picolinate to fruit flies. Both reported safety concerns. The Company engaged an independent contract research organization, BioReliance Corporation, and replicated the studies conducted by Stearns using Chromax chromium picolinate following internationally accepted procedures. The Company found its Chromax chromium picolinate to be safe. Experts have advised that fruit fly studies do not predict results in humans.

#### The Company's Proposed Therapeutic Branded Products

The Company is positioning its first branded product, Diachrome®, as an aid in the dietary management of diabetes, and it expects to market this product with the support of healthcare professionals. Diachrome is a patented combination of Chromax chromium picolinate and biotin; these are nutritional ingredients that work synergistically to enhance blood sugar control and improve blood cholesterol profiles. Building on pre-clinical and early clinical research, the Company has formed a strategic alliance with XLHealth, formerly known as Diabetex Corporation, a leading diabetes disease management company, to validate Diachrome's ability to significantly improve blood sugar control in people with type 2 diabetes. Together, the companies are conducting a 400+ patient double-blind placebo controlled trial aimed at demonstrating the pharmacoeconomic and health benefits associated with the use of Diachrome as a nutritional adjunct to current diabetes management protocols. The Diachrome study is expected to complete by the end of calendar year 2004 and, assuming positive results, Diachrome will be aggressively marketed to the diabetes healthcare market under the Nutrition 21 label, as a first line medical nutrition therapy for all patients diagnosed with type 2 diabetes.

XLHealth, in partnership with Omnicare Inc., has been awarded funding by the Centers for Medicare and Medicaid Services (CMS) to conduct a demonstration project where they will provide disease management, counseling, monitoring and education to 10,000 Medicare beneficiaries who are chronically ill with severe diabetes, congestive heart failure and cardiovascular disease. Through its alliance with XLHealth, the Company will also seek to include Diachrome on the Medicare formulary, and demonstrate the product's ability to improve patient outcomes and lower the cost of care. The Company plans a targeted direct-to-consumer marketing program to managed diabetic populations. The Company plans to build consumer awareness for its products through a media campaign that leverages research outcomes, in combination with consumer and physician testimonials. Communication of scientific findings will be used to build consensus within the healthcare community regarding the inherent value of the Company's products.

The Company holds patents for several other novel nutrition compounds and plans to expand its licensing program to include them once the Chromax expansion and Diachrome launch are underway.

#### Pharmaceutical Products Licensed to Third Parties

In August 2000, the Company exclusively licensed to Biosynexus certain rights to nisin and lysostaphin antibacterial technologies for development and marketing of new drugs for human uses. The Company received a payment of \$1.4 million, and the license provides for milestone payments of up to \$14 million, and royalties. The Company also received warrants to acquire

common stock of Biosynexus, currently a privately held company.

The Company also has infectious disease technology centered on nisin and lysostaphin for the treatment of diseases in animals, including a moistened towel using a nisin-based formulation for mastitis prevention that is used for preparing dairy cows for milking. The Company launched the product under its trademark Wipe Out® Dairy Wipes in April 1996. On December 30, 1999, the Company sold its Wipe Out Dairy Wipes business to ImmuCell Corporation (“ImmuCell”). On April 12, 2000, the Company exclusively licensed to ImmuCell worldwide rights to develop and market new antibacterial drugs for animals using the Company’s nisin technology.

## **Research and Development**

During the fiscal years ended June 30, 2004, 2003 and 2002, the Company spent approximately \$2.4 million, \$2.2 million, and \$1.0 million, respectively, on research and development. The Company’s research and development program is based on chromium and seeks to discover and substantiate the efficacy and safety of ingredients and products that have a significant nutritional therapeutic value to consumers. The primary research focus over the past few years has been in the area of diabetes and cardiovascular health. Discovering the mechanism of action of chromium picolinate and further confirming the beneficial effects of chromium picolinate in people with diabetes have been critical objectives. The Company is also researching therapeutic areas involving obesity, depression, bone and joint health, and women’s health.

This research effort has enabled the Company to identify patentable new combinations of chromium and new uses for chromium, and new food systems that can be enhanced by the inclusion of its ingredient systems.

## Clinical Studies, Presentations and Publications

The Company from time to time provides funding for clinical studies of its products to evaluate efficacy and mechanisms of action, and in other instances supplies chromium picolinate for use in studies for which it provides no funding. The Company believes that positive results in these studies, whether or not funded by it, provide benefits to the Company by furthering acceptance of its products. The Company also makes presentations at various meetings to gain acceptance of its products. The following information summarizes certain of these studies and details those studies that were funded by the Company. The information also summarizes several recent presentations and publications that relate to the Company’s products. In no case is the Company required to provide any further funding.

### Studies in progress

#### Chromax

The Company has supplied its Chromax chromium picolinate to Yale School of Medicine for a clinical study funded by National Institutes of Health that is evaluating “*Chromium Effects in Impaired Glucose Tolerance.*” This study focuses on the effects of chromium picolinate on both measures of glucose tolerance (glucose, insulin, OGTT) and brachial artery endothelial function,

and is designed to generate dietary chromium recommendations for reducing the risk of diabetes and associated diseases.

The Company has supplied Chromax chromium picolinate to Pennington Biomedical Research Center for a clinical study funded by National Institutes of Health that is evaluating "*Chromium and Insulin Action.*" This study focuses on the effects of chromium picolinate on glucose homeostasis, and is designed to generate dietary chromium recommendations for reducing the risk of diabetes and associated diseases.

The Company supplied Chromax chromium picolinate to the University of Pennsylvania for a clinical study funded by the National Institutes of Health that is entitled "*A Double Blind Randomized Controlled Clinical Trial of Chromium Picolinate on Clinical and Biochemical Features of the Metabolic Syndrome.*" This study is evaluating the effect of daily supplementation with chromium picolinate on insulin sensitivity in individuals with metabolic syndrome, and on glucose tolerance tests, HDL-C, triglycerides, body composition, BMI and blood pressure. This study will also provide the first human data on the effects of chromium picolinate supplementation on oxidative stress and inflammation, which are major risk factors in the progression of diabetes and cardiovascular disease.

#### Diachrome

The Company has supplied its Diachrome product (Chromax chromium picolinate and biotin) and paid \$700,000 to conduct a clinical study that is entitled "*A Randomized, Double Blinded, Placebo Controlled, Parallel Arm, Multicenter Study To Evaluate The Improvement In Glycemic Control, Lipid Levels, Quality Of Life And Healthcare Costs After Daily Administration Of Chromium Picolinate And Biotin In Patients With Type 2 Diabetes.*" The study is designed to provide data on the effects of Diachrome on diabetes risk factors, and is expected to reflect improvements effected by Diachrome in beta cell function and the risk of insulin resistance in type 2 diabetes patients. Any data that are positive should support Diachrome as an alternative nutritional therapy for diabetes patients.

#### Studies Completed in 2004

##### Chromax

The Company gave a \$900,000 research grant to Comprehensive Neuroscience Inc. to conduct a clinical study on "*The Effects of Chromium Picolinate in Atypical Depression.*" The study was a double-blind placebo-controlled trial of Chromax chromium picolinate in people with depression and symptoms that include carbohydrate cravings, weight gain and tiredness. Results from this study suggest that chromium picolinate exerts antidepressant effects in people with carbohydrate cravings and reduces their carbohydrate cravings.

#### Presentations and Publications in 2004

A paper on "*Determining The Safety Of Chromium Tripicolinate For Addition To Foods As A Nutrient Supplement*" was published in Food Chemical Toxicology. This paper concluded that chromium picolinate is safe for addition to foods as a supplement.

A poster presentation entitled "*Chromium Picolinate And Biotin Combination Improves Blood Sugar Control In People With Type 2 Diabetes*" was given at the International Diabetes Federation. This presentation showed beneficial effects of chromium picolinate and biotin combination (Diachrome) on lowering elevated glycosylated hemoglobin (HbA1c) in people with type 2 diabetes.

A poster presentation entitled "*Chromium With Biotin Combination Decreases Fasting And Post Prandial Glucose Levels In People With Type 2 Diabetes Mellitus*" was given at the North American Association of Study of Obesity. This presentation reported beneficial effects of chromium picolinate and biotin combination (Diachrome) on lowering post prandial and fasting blood glucose levels in people with type 2 diabetes.

A poster presentation entitled "*Program Including Chromium Picolinate And Biotin Helps To Improve Glycemic Control In Type 2 Diabetes*" was given at the First World Congress on Insulin Resistance Syndrome. This presentation reported beneficial effects of chromium picolinate and biotin combination (Diachrome) on improving glycemic control in people with type 2 diabetes.

A presentation entitled "*Improvement in Fasting Blood Glucose with the Combination of Chromium Picolinate and Biotin In Type 2 Diabetes Mellitus*" was given at the 64<sup>th</sup> Annual Scientific Meetings of American Diabetes Association. This presentation reported reductions in fasting blood glucose levels and fructosamine levels in people with type 2 diabetes.

A poster presentation entitled "*Chromium Picolinate And Biotin Combination Improves Coronary Risk Factors*" was given at AHA Council on Arteriosclerosis, Thrombosis and Vascular Biology 5<sup>th</sup> Annual Conference meeting. This presentation reported reductions in coronary risk lipids and lipoprotein levels in people with type 2 diabetes.

A poster presentation entitled "*The Combination of Chromium Picolinate And Biotin Improves Glycemic Control In Patients With Type 2 Diabetes Mellitus*" was given at a meeting of the at 64<sup>th</sup> Annual Scientific Meetings of American Diabetes Association. This presentation discussed beneficial effects of chromium picolinate and biotin combination (Diachrome) in reducing glycosylated hemoglobin (HbA1c) in people with type 2 diabetes.

A presentation entitled "*Chromium and Insulin Resistance*" was given at a meeting of the Federation of American Societies for Experimental Biology. This presentation summarized several recent presentations and publications that demonstrate chromium picolinate efficacy and safety.

#### Studies Completed in 2003

##### Chromax

The Company supplied its Chromax chromium picolinate to the University of Vermont for a clinical study that was funded by the American Diabetes Association. The study is entitled "*Evaluation of the Effect of Chromium Picolinate in People with Type 2 Diabetes,*" and is designed to evaluate the effect of Chromax chromium picolinate on insulin sensitivity in people with type 2 diabetes. The study reported that chromium picolinate supplementation improved

glycemic control in people with type 2 diabetes through enhancement of insulin action in cellular signaling.

#### Presentations and Publications in 2003

An article on "*Chromium and Cardiovascular Disease*" was published in *Advances in Heart Failure* (International Academy of Cardiology). This article reviewed the significant beneficial effects of chromium picolinate on coronary heart disease risk factors, such as lipids and lipoproteins, in both animal and human studies.

A poster presentation entitled "*Glucose Uptake Of Chromium Picolinate, Chromium Polynicotinate And Niacin*" was presented at a meeting of the Federation of American Societies for Experimental Biology. This presentation reported on chromium picolinate enhancement of glucose uptake in skeletal muscle cells.

A poster presentation on "*Chromium Picolinate Increases Skeletal Muscle PI3 Kinase Activity in Obese, Hyperinsulinemic JCR:LA Corpulent Rats*" was presented at the 63rd annual meeting and scientific sessions of the American Diabetes Association. The presentation reported a mechanism of action by which chromium picolinate enhances insulin activity.

#### Studies Completed in 2002

##### Diachrome

The Company gave a \$200,000 research grant and supplied Diachrome to the Chicago Center for Clinical Research to conduct a "*Study On Chromium With Biotin Decreases Coronary Risk Lipids And Lipoproteins In People With Type 2 Diabetes Ingesting Moderate Carbohydrate Nutritional Beverages.*" Results from this trial showed that chromium picolinate and biotin can significantly reduce elevations in blood glucose levels and symptoms of fatigue in people with type 2 diabetes that are consuming a carbohydrate-containing beverage. These findings were presented at the Federation of American Societies for Experimental Biology, and American College of Nutrition.

##### Chromax

The Company gave a \$110,000 research grant and supplied Chromax to Duke University to study the "*Effectiveness of Chromium Picolinate in Atypical Depression: A Placebo-Controlled Clinical Trial.*" Results from this study showed that chromium picolinate helped reduce depression markers. In this study, seventy percent (70%) of chromium picolinate group and zero percent (0%) of placebo group responded to treatment. This study was published in *Biological Psychiatry*.

#### Presentations and Publications in 2002

A paper entitled "*Oral Chromium Picolinate Improves Carbohydrate And Lipid Metabolism And Enhances Skeletal Muscle Glut-4 Translocation In Obese, Hyperinsulinemic (JCR-LA Corpulent) Rats*" was published in *The Journal of Nutrition* 2002. This article reported that chromium

picolinate helps in treatment of the insulin resistance syndrome. Chromium picolinate supplementation was also shown to enhance insulin sensitivity, glucose metabolism and blood lipids.

A poster presentation entitled "*Antimutagenic Activity Of Chromium Picolinate In The Salmonella Assay*" was presented at XIV World Congress of Pharmacology. The presentation reported that chromium picolinate is non-mutagenic.

### **Governmental Regulation**

The U.S. Food and Drug Administration ("FDA") regulates the labeling and marketing of the Company's dietary supplements under the Dietary Supplement and Health Education Act ("DSHEA"). Under DSHEA, dietary supplements that were first marketed as dietary supplements after October 1994 require safety approval by the FDA. The Company's products did not require FDA safety approval because they were marketed as dietary supplements prior to October 1994. See "The Company's Existing Ingredient Business" for further information on the safety of the Company's products. Under DSHEA, the Company is required to submit for FDA approval claims regarding the effect of its dietary supplements on the structure or function of the body. DSHEA also requires an FDA approval for claims that relate dietary supplements to disease prevention (so-called "health claims"). To enhance its market applications, the Company has elected to seek FDA approval for health claims that its products can prevent diabetes and possibly other diseases.

The Federal Trade Commission ("FTC") regulates product-advertising claims and requires that claims be supported by competent and reliable scientific evidence. Prior to the Company's acquisition of a California limited partnership called Nutrition 21 ("Nutrition 21 LP"), the FTC opened an inquiry into certain of the claims that Nutrition 21 LP was making for chromium picolinate. The inquiry was terminated by Nutrition 21 LP and the FTC entering into a consent decree that requires that claims be supported by competent and reliable scientific evidence. After the Company acquired Nutrition 21 LP, the Company undertook new clinical studies to support the claims it intended to make for its products. The FTC has subsequently audited the Company's chromium picolinate advertising and has not found either a lack of competent and reliable scientific evidence or a failure by the Company to comply with the consent decree. The FTC continues to monitor the Company's advertising and could limit its advertising in ways that could make marketing its products more difficult or result in lost sales.

### **Proprietary Rights**

#### Trademarks

Chromax, Diachrome, Selenomax, SelenoPure, Zinmax, Zenergen, and Magnemax are among the more well known trademarks owned by Nutrition 21: Chromax for chromium picolinate; Diachrome for chromium picolinate and biotin; Selenomax for high selenium yeast, SelenoPure for yeast-free selenium; Zinmax for zinc picolinate; Zenergen for chromium picolinate and conjugated linoleic acid, and Magnemax for manganese picolinate.

## Nutrition Patents

The Company presently has 36 issued US patents and 13 pending US patent applications with foreign equivalents covering novel compositions and therapies directed towards significant health conditions such as cardiovascular disease, depression, polycystic ovary syndrome, both type 1 and type 2 diabetes, and sports nutrition.

Of these patents, 24 U.S. patents and various foreign patents relate to chromium, including composition of matter patents for novel chromium picolinate complexes and their uses. Three of these patents relate to the accepted essential nutritional uses of chromium picolinate for glucose control, for managing cholesterol, and for increasing lean body mass and reducing body fat, and are in force through 2009. Patents for improved chromium picolinate complexes containing combinations of chromium and various nutrients for enhancing the benefits of chromium picolinate, are in force into the year 2017. More recently, the Company has secured patent rights to the uses of all forms of chromium in the treatment of depression and other mood disorders, rights that are in force through 2018.

The pending applications build upon the Company's expertise in technology areas such as nutritional mineral supplements, and are directed towards the synergistic effects of combining chromium with compounds such as biotin, alpha lipoic acid, conjugated linoleic acid (CLA), and CLA isomers. These include issued and pending patent applications covering the positive effects of chromium and biotin on type 2 diabetes. Outside of the chromium area, the Company continues to file patent applications in the area of arginine silicate, a patented compound that has shown promise in therapies for bone and joint health, cardiovascular disease, and glucose metabolism.

The Company maintains non-disclosure safeguards, including confidentiality agreements, with employees and certain consultants. There can be no assurance, however, that others may not independently develop similar technology or that secrecy will not be breached despite any agreements that exist.

Although the Company holds exclusive rights to United States patents for the nutritional uses for which chromium picolinate is sold, the Company is often faced with competition from companies, including importers, that disregard its patent rights. These companies take calculated risks that the Company will not sue to enforce its patent rights against them. The Company determines whether to file suit against an infringer by taking into consideration an estimate of infringing sales and the cost of patent enforcement. While there is no guarantee that the Company will be able to successfully enforce its patent rights against these competitors, the Company continues to monitor industry practices.

The Company has initiated several patent infringement cases that it subsequently settled. In 2003, the Company settled a patent dispute with Lonza Inc., in which Lonza agreed to license the Company's glucose control patents for marketing Lonza's proprietary combination of carnitine and chromium picolinate for swine feed applications. No other rights were granted to Lonza to sell chromium picolinate, alone or in other combinations, for human or other animal applications.

## Pharmaceutical Patents

The Company owns more than 200 patents relating to, among other things, the expression and production of proteins by recombinant Bacillus strains; plasmid vectors and methods of construction; expression and production of recombinant lysostaphin; novel bacteriocin compositions and their use as broad spectrum bactericides; the use of bacteriocin compositions to treat bovine mastitis; the use of bacteriocin compositions in oral healthcare; the use of bacteriocin compositions on skin for healthcare and hygiene; and the use of bacteriocin compositions in gastrointestinal healthcare. These patents are licensed to Biosynexus Incorporated, and ImmuCell Corporation as set forth under "Pharmaceutical Products Licensed to Third Parties."

The Company maintains trade secret protection for bacterial strains, technical know-how, and other information it considers proprietary and beneficial for the manufacture, use, regulatory approval, and marketing of the Company's products.

## **Competition**

In considering its competitive position, the Company distinguishes between its existing ingredients business, on the one hand, and its prospective therapeutic branded products, on the other hand. The Company has a relatively strong position for its current chromium sales where it believes that it has an approximately 80% share of the market for stand alone sales, and it has a 15% market share for sales of chromium into multi-ingredient products, based on SPINS and IRI data reporting retail sales of chromium products. The Company's major competitors in the chromium industry are Albion Labs, Kelatron, and InterHealth Nutraceuticals Inc.

The Company's proposed therapeutic branded business will confront many large established companies in a huge industry that serves the diabetes management market. The Company's success in this arena will in large part depend on its ability to obtain a scientific consensus that its supplement offer benefits that are competitive with the numerous companies that participate in this business.

The nutritional product industry and the related drug industries are, of course, intensely competitive. The great majority of these competitors have financial and technical resources as well as production and marketing capabilities substantially greater than the Company. In addition, many competitors have significantly greater experience in the development and testing of new or improved products.

## **Supply and Manufacturing**

The Company has a manufacturing agreement with a third party for the manufacture of the Company's principal products. There are numerous sources of supply for the raw materials that the Company's manufacturers use to manufacture the Company's products. The Company has never experienced a shortage of ingredient products.

The Company keeps on hand an average of four months' inventory. The Company believes that it has adequate inventory to accommodate a suspension in the manufacture of any of its products

by its current manufacturers, and that it could in any event resort to other manufacturers with minimal disruption.

The Company plans to continue to outsource the manufacturing and packaging needs as it expands its business to include its marketing and distribution of branded therapeutic supplements.

### **Employees**

As of June 30, 2004, the Company had 28 full-time employees, of whom 3 were executive employees, 8 were administrative, 12 were engaged in marketing and sales, and 5 were involved in research, process and product development, and manufacturing. The Company does not have a collective bargaining agreement with any of its personnel and considers its relationship with its employees to be satisfactory.

### **Item 2. PROPERTIES**

Since September 1998, the Company maintains its headquarters pursuant to a seven and one-half year lease at 4 Manhattanville Road, Purchase, New York 10577-2197 (Tel: 914-701-4500). In fiscal 2002, the Company's surrendered a portion of its leased premises, and received a reduction in its annual rental for its headquarters location from \$589,420 to \$370,443 which sum is due in monthly installments. The rent is subject to annual increases over the term of the lease based on increases in certain building operating expenses.

### **Item 3. LEGAL PROCEEDINGS**

On March 19, 2003, Andrew Wertheim (a former Executive Officer) initiated an arbitration with the American Arbitration Association against the Company in connection with his termination of employment. On July 24, 2004, an arbitrator awarded Mr. Wertheim (1) damages of \$268,477 for salary and benefits, (2) \$708,750 related to stock options, and (3) interest of \$92,151. The Company believes that the arbitrator's award is in error. Accordingly, on August 3, 2004, the Company filed an action in the United States District Court for the Southern District of New York against Mr. Wertheim seeking to vacate the arbitration award. On August 16, 2004, the Company filed a Motion to Vacate the part of the award that relates to the stock options, i.e. \$708,750 plus interest.

The Company and the Federal Trade Commission (FTC) are discussing whether the Company should have any liability for weight loss advertising claims that were made on QVC, Inc. for the Company's Lite Bites® products. On March 24, 2004, the FTC sued QVC in the U.S. District Court for the Eastern District of Pennsylvania for these claims and for claims made on QVC for other products. QVC has in the same lawsuit filed on April 14, 2004, Third-Party Complaints for damages against six parties including the Company (Third-Party Defendants). The FTC and the Third-Party Defendants have filed Motions to Strike QVC's Third-Party Complaints. The Company discontinued the Lite Bites product line in fiscal year 2003. Neither the FTC nor QVC has set forth an amount being sought as damages, nor can the Company estimate its exposure.

On September 3, 2004, QVC filed a suit against the Company alleging that QVC has the right to return product to the Company and receive a payment of \$551,715, and for \$5,706 for certain services QVC allegedly rendered to the Company. QVC's purchase orders provide QVC the

right to return product, provided the requests for return are made within certain time periods. The Company has reviewed its records and believes that QVC's requests for return were not timely. The Company is unable to predict the outcome of this matter.

The Company in the ordinary course of its business has brought patent infringement actions against companies that are selling chromium picolinate in violation of the Company's patent rights. As of this date, no actions are ongoing, and the Company, which intends to vigorously protect its proprietary rights, is evaluating bringing other patent infringement actions. Various actions have been terminated on terms that the Company believes will protect its rights.

**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to the Company's shareholders during the fiscal quarter ended June 30, 2004.

## PART II

### Item 5. MARKET PRICE OF REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

#### Matters Relating to Common Stock

The Company's Common Stock trades on the Nasdaq SmallCap Market System under the symbol "NXXI".

The Company has not paid a cash dividend to its public shareholders on its Common Stock. The Company intends to retain all earnings, if any, for the foreseeable future for use in the operation and expansion of its business and, accordingly, the Company does not contemplate paying any cash dividends on its Common Stock in the foreseeable future.

The following table sets forth the high and low sales prices as reported by the Nasdaq Market for the Common Stock.

Fiscal Quarter Ended	<u>Common Stock</u>	
	High	Low
September 30, 2002	\$0.40	\$0.37
December 31, 2002	\$0.64	\$0.48
March 31, 2003	\$0.38	\$0.35
June 30, 2003	\$0.48	\$0.44
September 30, 2003	\$1.66	\$0.77
December 31, 2003	\$1.25	\$0.99
March 31, 2004	\$1.03	\$0.84
June 30, 2004	\$1.31	\$0.69

As of September 17, 2004, there were approximately 471 holders of record of the Common Stock. The Company believes that the number of beneficial owners is substantially greater than the number of record holders, because a large portion of its Common Stock is held of record in broker "street names."

#### **Adoption of Shareholders Rights Plan**

The Company adopted a Shareholder Rights Plan on September 12, 2002. Under this plan, the Company distributed, as a dividend, one preferred share purchase right for each share of Common Stock of the Company held by stockholders of record as of the close of business on September 25, 2002. The Rights Plan is designed to deter coercive takeover tactics, including

the accumulation of shares in the open market or through private transactions, and to prevent an acquiror from gaining control of the Company without offering a fair price to all of the Company's stockholders. The Rights will expire on September 11, 2012.

Each Right entitles stockholders to buy one one-thousandth of a share of newly created Series H Participating Preferred Stock of the Company for \$3.00 per share. Each one one-thousandth of a share of the Preferred Stock is designed to be the functional equivalent of one share of Common Stock. The Rights will be exercisable only if a person or group acquires beneficial ownership of 15% or more of the Company's Common Stock (30% in the case of a person or group that is currently a 15% holder) or commences a tender or exchange offer upon consummation of which such person or group would beneficially own 15% or more of the Company's Common Stock.

If any person or group (an "Acquiring Person") becomes the beneficial owner of 15% or more of the Company's Common Stock (30% in the case of a person that is currently a 15% holder), then (1) the Rights become exercisable for Common Stock instead of Preferred Stock, (2) the Rights held by the Acquiring Person and certain affiliated parties become void, and (3) the Rights held by others are converted into the right to acquire, at the purchase price specified in the Right, shares of Common Stock of the Company having a value equal to twice such purchase price. The Company will generally be entitled to redeem the Rights, at \$.001 per Right, until 10 days (subject to extension) following a public announcement that an Acquiring Person has acquired a 15% position.

## Item 6. SELECTED FINANCIAL DATA

The following tables summarize selected consolidated financial data that should be read in conjunction the more detailed financial statements and related footnotes and management's discussion and analysis of financial condition and results of operations included herein. Figures are stated in thousands of dollars, except per share amounts.

Selected Statement of Operations Data:	Year Ended June 30,				
	2004	2003 <sup>(2)</sup>	2002 <sup>(1)</sup>	2001	2000
Total Revenues	\$10,232	\$10,615	\$14,668	\$23,252	\$32,814
Gross Profit	8,113	6,486	10,324	17,036	27,034
Operating (Loss) Income	(5,854)	(11,081)	(7,789)	(955)	7,041
(Loss) Income Before Taxes	(5,833)	(11,050)	(6,011)	1,400	7,004
Income Taxes	68	(544)	--	335	523
Net (Loss) Income	(5,901)	(10,506)	(6,011)	1,065	6,490
Diluted (Loss) Earnings per Common Share	(0.16)	(0.32)	(0.19)	0.03	0.20

  

Selected Balance Sheet Data:	At June 30,				
	2004	2003	2002	2001	2000
Working Capital	\$3,413	\$4,146	\$8,002	\$6,392	\$6,486
Total Assets	16,367	18,920	28,100	38,887	41,085
Total Liabilities	3,734	3,484	2,151	6,495	10,430
Long-Term Obligations	--	--	--	122	1,278
Redeemable Preferred Stock	--	--	--	418	676
Stockholders' Equity	12,633	15,436	25,949	31,974	29,979

(1) Consolidated Statements of Operations include a \$7.1 million non-cash charge for the impairment of goodwill.

(2) Consolidated Statements of Operations include a \$4.4 million non-cash charge for the impairment of intangibles.

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

The following discussion should be read in conjunction with the Consolidated Financial Statements and related notes thereto of the Company included elsewhere herein.

**Overview**

The Company's revenues are primarily derived from the sale of proprietary ingredients and the grant of patent licenses related to those ingredients to manufacturers of vitamin and mineral supplements. The fee for the licenses is bundled on an undifferentiated basis with the price that the Company charges for its ingredients.

Cost of goods sold includes both direct and indirect manufacturing costs. Research and development expenses include internal expenditures as well as expenses associated with third party providers. Selling, general and administrative expenses include salaries and overhead, third party fees and expenses, royalty expenses for licenses and trademarks, and costs associated with the selling of the Company's products. The Company capitalizes patent costs and intangible asset costs, and amortizes them over periods of one to seventeen years.

The following table sets forth items in the Consolidated Statements of Operations as a percent of revenues:

	Fiscal Year Percent of Revenues		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Total Revenues	100.0%	100.0%	100.0%
Gross profit*	78.8	59.8	69.7
Selling, general and administrative expense	88.8	77.3	50.1
Research and development expense	23.3	21.0	6.9
Operating (loss)	(57.2)	(104.4)	(53.1)
Net (loss)	(57.7)	(99.0)	(41.0)

\*Based upon percent of net sales

**Results of Operations**

1. Year ended June 30, 2004 vs. year ended June 30, 2003

**Revenues**

Net sales of \$10.0 million for fiscal year 2004 declined \$0.3 million when compared to net sales of \$10.3 million for fiscal year 2003.

The Company's decision to discontinue its investment in the Lite Bites product line in fiscal year 2003 resulted in a \$0.9 million decline in revenue in fiscal year 2004. Partially offsetting the decline was a \$0.6 million improvement in net sales of its Chromax chromium picolinate

products. Net sales were bolstered by the positive effect of a price increase introduced in fiscal year 2003.

Other revenue from license fees for fiscal year 2004 was \$0.2 million and \$0.4 million in fiscal year 2003.

#### Cost of Goods Sold

Cost of goods sold in fiscal year 2004 of \$2.1 million declined \$2.0 million when compared to \$4.1 million in fiscal year 2003. The reduction in cost of goods sold is directly related to the Company's decision to discontinue its investment in the Lite Bites product line. Gross margin on product sales was 78.8% in fiscal year 2004 compared to 59.8% in fiscal year 2003. The improvement is directly related to gross margins on nutritional products sales, which are greater than gross margins on Lite Bites products.

#### Selling, General and Administrative

Selling, general and administrative expense (SG&A) of \$9.1 million for fiscal year 2004 increased \$0.9 million when compared to \$8.2 million in fiscal year 2003. Excluding a \$1.1 million charge for termination benefits related to an employment matter, SG&A decreased \$0.2 million when compared to the comparable period a year ago. Reduction in personnel and personnel related costs was the primary reason for the improvement.

#### Research and Development

Research and development expense in fiscal year 2004 was \$2.4 million compared to \$2.2 million in fiscal year 2003. The increase is due primarily to costs for continued research for new chromium applications.

The Company's therapeutic strategy continues to include a commitment to spending on research and development and is targeted at further validating earlier findings focused on disease specific conditions in the areas of diabetes and depression.

In fiscal year 2003, the Company entered into an agreement with XLHealth, formerly known as Diabetex Corporation, a diabetes disease management company, to fund a 400+ patient double blind placebo controlled trial to evaluate Diachrome's effect as a nutritional adjunct to standard care for people with diabetes. This Diachrome study is expected to be completed by the end of calendar year 2004.

The Company expects to launch these products under the Dietary Supplement Health and Education Act (DSHEA) regulatory pathway that is less costly and less time consuming than that required for drug development. These large-scale studies are being conducted to secure medical acceptance and adoption for the Company's products as standard treatment protocols. The Company's spending in these areas of new technology is discretionary and is subject to the availability of funds. There can be no assurances that the Company's disease specific product development efforts will be successfully completed or that the products will be successfully manufactured or marketed.

## Operating Loss

Operating loss for fiscal year 2004 was \$5.9 million, an improvement of \$5.2 million when compared to an operating loss of \$11.1 million in fiscal year 2003. Fiscal year 2003 included a \$4.4 million non-cash charge for impairment of long-lived assets. In addition, an increase in gross profit in fiscal year 2004 of \$1.6 million when compared to fiscal year 2003 contributed to the reduction in the company's operating loss. Partially offsetting the improvement was a net increase of \$0.8 million in operating expenses, due primarily to costs accrued for termination benefits related to an employment matter.

## 2. Year ended June 30, 2003 vs. Year ended June 30, 2002

### Revenues

Net sales of \$10.3 million for fiscal year 2003 declined \$4.0 million when compared to net sales of \$14.3 million for fiscal year 2002.

The decline in revenues primarily reflects unsatisfactory results in the marketing of the Company's Lite Bites product line. Lower sales to the QVC channel can be partially attributable to increased competition in the nutrition bar category and a general decline in the weight-loss supplement market related to negative press associated with the ephedra controversy. Softer sales resulted in more limited airtime driving the Lite Bites business on QVC into further decline. In parallel during fiscal year 2003, the Company continued to explore alternative cost-effective channels of distribution for the Lite Bites brand that, prior to this year, was by agreement sold exclusively through QVC. The Company tested the proposition of taking Lite Bites into retail distribution through an alliance with Leiner Health Products, one of the largest and most reputable supplement distributors in the U.S. The resulting feedback indicated that the brand would require a much larger investment in marketing than the Company believed was justified. Therefore, the Company has made the decision to discontinue the Lite Bites product line. As a result, the Company determined that a \$4.4 million non-cash charge associated with the long-lived assets related to the Lite Bites product line was warranted. The Company will consider a sale of the Lite Bites assets. Any returns realized will be reinvested in the expansion of the Company's chromium-derived business opportunities.

Lower weight-loss and sports nutrition supplement sales have led to commensurate reductions in revenues from ingredient sales.

Other revenue from license fees for fiscal year 2003 and fiscal year 2002 was \$0.4 million.

### Cost of Goods Sold

Cost of goods sold in fiscal year 2003 of \$4.1 million declined \$0.2 million when compared to \$4.3 million in fiscal year 2002. A reduction in cost of goods sold, which is directly related to lower sales in fiscal year 2003, was partially offset by a charge of \$0.2 million for slow-moving inventory of the Lite Bites product line. Gross margin on product sales was 59.8% in fiscal year 2003, compared to 69.7% in fiscal year 2002. The decline was due primarily to product mix and charges to cost of goods sold for slow-moving inventory.

### Selling, General and Administrative

Selling, general and administrative expense for fiscal year 2003 of \$8.2 million increased \$0.9 million when compared to \$7.3 million for fiscal year 2002. Marketing and related expenditures increased \$0.5 million while personnel and personnel-related costs associated with organizational expansion to support the Company's planned launch of new chromium based therapeutic products increased \$0.4 million.

### Research and Development

Research costs of \$2.2 million for fiscal year 2003 increased \$1.2 million when compared to \$1.0 million in fiscal year 2002. The increase is due primarily to studies related to the Company's anti-depressant technology (\$1.0 million) as well as increased expenditures for its Diachrome studies (\$0.2 million).

The Company's therapeutic strategy for the past year includes a larger commitment to spending on research and development and is targeted at further validating earlier findings focused on disease specific conditions in the areas of diabetes and depression.

The Company entered into an agreement with XLHealth, formerly known as Diabetex Corporation, a diabetes disease management company, and is funding a large-scale trial in managed patient populations to evaluate Diachrome's effect as a nutritional adjunct to standard care for people with diabetes.

The Company also entered into an agreement with Comprehensive NeuroSciences, Inc., a contract research organization in the neurosciences field, to perform studies related to the Company's anti-depressant technology. The Company expects that the first phase of its study will be completed during fiscal year 2004.

The Company expects to launch these products under the Dietary Supplement Health and Education Act (DSHEA) regulatory pathway that is less costly and less time consuming than that required for drug development. These large-scale studies are being conducted to secure medical acceptance and adoption for the Company's products as standard treatment protocols. The Company's spending in these areas of new technology is discretionary and is subject to the availability of funds. There can be no assurances that the Company's disease specific product development efforts will be successfully completed or that the products will be successfully manufactured or marketed.

### Impairment of Intangibles

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." This statement supercedes FASB Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." The statement requires the Company to review its long-lived assets whenever events or changes in circumstances indicate that impairment might exist. During fiscal year 2003, the Company decided to discontinue investing in its Lite Bites product line. As a result of a review of current and forecasted operating cash flows and the profitability of this line, the Company determined that a \$4.4 million non-cash impairment charge was warranted.

### Operating Loss

Operating loss for fiscal year 2003 was \$11.1 million, including a \$4.4 million non-cash charge for impairment of long-lived assets, compared to an operating loss of \$7.8 million in fiscal year 2002, which included a \$7.1 million non-cash charge for impairment of goodwill.

### Income Taxes

The effective tax rate for fiscal year 2003 was a benefit of 5% compared to 0% for fiscal year 2002. For fiscal year 2003, the benefit was recorded up to the extent of the Company's net operating loss carryback. The difference between the federal statutory rate of 34% and the actual rate is primarily due to changes in the deferred tax asset valuation allowance.

### Liquidity and Capital Resources

Cash and cash equivalents and short-term investments at June 30, 2004 of \$4.2 million increased \$0.1 million when compared to \$4.1 million at June 30, 2003. As of June 30, 2004, the Company had a working capital surplus of \$3.4 million, compared to a working capital surplus of \$4.1 million at June 30, 2003. Changes in working capital included an increase in trade receivables and a decrease in other receivables of \$0.2 million and \$0.8 million, respectively, as well as an increase of \$0.2 million in accounts payable and accrued expenses.

Net cash used in operating activities for fiscal year 2004 was \$2.5 million compared to cash used in operating activities of \$0.3 million in fiscal year 2003. Net increases in operating assets of \$1.0 million and decreases in accounts payable and accrual expenses of \$1.1 million were the primary reasons for the change.

Net cash used in investing activities for fiscal year 2004 was \$2.4 million compared to cash provided by investing activities of \$0.5 million in fiscal year 2003. \$2.0 million was invested in short-term instruments in fiscal year 2004 compared to the redemption of \$1.0 million in short-term instruments in fiscal year 2003.

Net cash provided by financing activities was \$3.0 million for fiscal year 2004 compared to net cash used in financing activities of \$58 thousand in fiscal year 2003. Net proceeds of \$3.0 million from a private placement was the primary reason for the change.

The Company's primary source of financing in fiscal year 2004 was proceeds from a private placement. The Company believes that cash on hand will provide sufficient liquidity in the short term. Long term liquidity is dependent upon achieving future profitability or raising additional financing.

Future increases in marketing and research and development expenses over the present levels and any acquisition activities will require additional funds. The Company intends to seek any necessary additional funding through arrangements with corporate collaborators, through public or private sales of its securities, including equity securities, or through bank financing arrangements. The Company does not currently have any specific arrangements for additional financing and there can be no assurance that additional funding will be available at all or on terms acceptable to the Company.

### Critical Accounting Policies and Estimates

The preparation of the consolidated financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, the Company evaluates its estimates, including those related to uncollectible accounts receivable, inventories, goodwill, intangibles and other long-lived assets. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its consolidated financial statements:

- The Company maintains allowances for uncollectible accounts receivable for estimated losses resulting from the inability of its customers to make required payments. If the financial condition of the Company's customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.
- The Company carries inventories at the lower of cost or estimated net realizable value. If actual market conditions are less favorable than those projected by management write-downs may be required.
- Property, plant and equipment, patents, trademarks and other intangible assets owned by the Company are amortized, over their estimated useful lives. Useful lives are based on management's estimates over the period that such assets will generate revenue. Intangible assets with definite lives are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Future adverse changes in market conditions or poor operating results of underlying capital investments or intangible assets could result in losses or an inability to recover the carrying value of such assets, thereby possibly requiring an impairment charge in the future.

### Significant Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 150, "Accounting for Financial Instruments with Characteristics of both Liabilities and Equity." SFAS No. 150, establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. The Company believes this pronouncement will have no effect on its operations.

### **Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Market risk represents the risk of changes in value of a financial instrument, derivative or non-derivative, caused by fluctuations in interest rates, foreign exchange rates and equity prices. The Company has no financial instruments that give it exposure to foreign exchange rates or equity prices.

**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements are included herein commencing on page F-1.

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

At a meeting held on July 29, 2003, the Audit Committee of the Board of Directors of the Company approved the engagement of J. H. Cohn LLP as its independent registered public accounting firm for the fiscal year ended June 30, 2003 to replace the firm of Ernst & Young LLP, who were dismissed as auditors of the Company effective July 31, 2003.

The audit reports of Ernst & Young LLP on the consolidated financial statements of Nutrition 21, Inc. as of and for the years ended June 30, 2002 and 2001, did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope, or accounting principles. There were no disagreements between the Company and Ernst & Young LLP on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which, if not resolved to Ernst & Young LLP's satisfaction, would have caused Ernst & Young LLP to make reference to the subject matter of such disagreements in connection with its report.

**Item 9A. CONTROLS AND PROCEDURES**

The Company maintains disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the specified time periods. As of June 30, 2004, the Company's Chief Executive Officer and Chief Financial Officer evaluated, with the participation of the Company's management, the effectiveness of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Based on the evaluation, which disclosed no significant deficiencies or material weaknesses, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective. There were no significant changes in the Company's internal controls over financial reporting that occurred during the Company's most recent fiscal quarter that have materially affected or are reasonably likely to materially affect the Company's internal control over financial reporting.

### PART III

#### Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

##### Officers and Directors

The officers and directors of the Company are as follows:

Name and Age	Year Joined Company	Position
Gail Montgomery (51)	1999	President, Chief Executive Officer, and Director
John H. Gutfreund (74)	2000	Chairman of the Board
P. George Benson, PhD (58)	1998	Director
Warren D. Cooper, MD (51)	2002	Director
Audrey T. Cross, PhD (59)	1995	Director
Paul Intlekofer (36)	2002	Chief Financial Officer and Senior Vice President, Corporate Development
Marvin Moser, MD (80)	1997	Director
Robert E. Pollack, PhD (64)	1995	Director
Benjamin T. Sporn (66)	1986	Senior Vice President, General Counsel, and Secretary

Gail Montgomery has been President, Chief Executive Officer and a Director of the Company since September 29, 2000, when she succeeded Fredrick D. Price. From July 1999 to September 2000, she served the Company's Nutrition 21 subsidiary in various capacities, most recently as Vice President and General Manager. From November 1998 to July 1999, Ms. Montgomery was President of Health Advantage Consulting, a consulting firm, which provided strategic planning, new product introduction, and market development services to the nutrition industry. From 1992 to 1998 she worked for Diet Workshop, a diet franchise network, most recently as President and CEO. From 1979 to 1992, Ms. Montgomery has served in various capacities in the health and fitness sector. She received a BA from Douglas College of Rutgers University in communications.

P. George Benson, PhD, was elected a Director of the Company in July 1998. Dr. Benson is Dean of the Terry College of Business and holds the Simon S. Selig, Jr. Chair for Economic Growth at the University of Georgia. Dr. Benson was previously the Dean of the Faculty of Management at Rutgers University and a professor of decision sciences at the Carlson School of Management of the University of Minnesota. In 1997, he was appointed by the U.S. Secretary of Commerce to a three-year term as one of the nine judges for the Malcolm Baldrige National Quality Award. In 1996, Business News New Jersey named Dr. Benson one of New Jersey's "Top 100 Business People". He received a BS from Bucknell University and a PhD in business from the University of Florida.

Warren D. Cooper, MD was elected a Director of the Company in April 2002. Dr. Cooper is president and founder of Coalescence, Inc., a consultancy focused on business and product development for the pharmaceutical and healthcare industries. From 1995 to 1999, Dr. Cooper was the business unit leader of Cardiovascular Business Operations at AstraZeneca Pharmaceuticals LP. For three years before that he was executive director of the Medical Affairs & Drug Development Operations in the Astra/Merck Group of Merck & Co. Over a five-year period from 1987 to 1992, Dr. Cooper served as executive director for Worldwide Clinical Research Operations and as senior director for Clinical Research Operations (Europe) at Merck Research Laboratories. He was with Merck, Sharp & Dohme, U.K., from 1980 to 1987, first as a clinical research physician and later as director of medical affairs. Dr. Cooper is a member of the Medical Advisory Board of Zargis Medical Corp. (a Siemens joint venture). He also holds memberships in the American Association of Pharmaceutical Physicians, the American Society of Hypertension and the International Society of Hypertension. He received a B.Sc. in physiology and an M.B. B.S. (U.K. equivalent to U.S. MD) from The London Hospital Medical College, University of London.

Audrey T. Cross, PhD, was elected a Director of the Company in January 1995. Dr. Cross has been Associate Clinical Professor at the Institute of Human Nutrition at the School of Public Health of Columbia University since 1988. She also works as a consultant in the areas of nutrition and health policy. She has served as a special assistant to the United States Secretary of Agriculture as Coordinator for Human Nutrition Policy and has worked with both the United States Senate and the California State Senate on nutrition policy matters. Dr. Cross received a BS in dietetics, a Master of Public Health in nutrition and a PhD from the University of California at Berkeley, and a JD from the Hastings College of Law at the University of California at San Francisco.

John H. Gutfreund was elected a Director of the Company in February 2000 and Chairman of the Board in September 2001. Mr. Gutfreund is Senior Managing Director and Executive Committee Member of C. E. Unterberg, Towbin, investment bankers, and President of Gutfreund & Company, Inc., a New York-based financial consulting firm that specializes in advising select corporations and financial institutions in the United States, Europe and Asia. He is the former chairman and chief executive officer of Salomon Inc., and past vice chairman of the New York Stock Exchange and a past board member of the Securities Industry Association. Mr. Gutfreund is active in the management of various civic, charitable, and philanthropic organizations, including the New York Public Library, Montefiore Medical Center, The Brookings Institution, Council on Foreign Relations, Honorary Trustee, Oberlin (Ohio) College, and Chairman of the Aperture Foundation. Mr. Gutfreund is also a director of AccuWeather, Inc., Evercel Inc., LCA-Vision, Inc., Maxicare Health Plans, Inc., The LongChamp Core Plus Fund Ltd., and The Universal Bond Fund. He received a BA from Oberlin College.

Paul Intlekofer was elected Chief Financial Officer and Senior Vice President, Corporate Development, on January 17, 2003. From June 2002 to January 2003, he served the Company in varying capacities. From September 2001 to June 2002, Mr. Intlekofer was Senior Vice President of Planit, Inc., which provided strategic planning, capital formation, M&A, marketing and new product development services to the healthcare and financial industries. From 1998 to 2001 he was Senior Vice President of Corporate Development for Rdental LLC, the exclusive technology alliance of the American Dental Association and oral health content provider of WebMD. From 1995 to 1997 he was Director of Strategic Operations/Business Development for Doctors Health, a practice management and health insurance company. Early in his career, he practiced corporate and securities law for Venable, Baetjer & Howard. Mr. Intlekofer received

his MBA and Juris Doctor from the University of Maryland and BA from the Johns Hopkins University.

Marvin Moser, MD was elected to the Board of Directors in October 1997. He is clinical professor of medicine at Yale and senior medical consultant at the National High Blood Pressure Education Program of the National Heart, Lung and Blood Institute. Dr. Moser's work has focused on various approaches to the prevention and treatment of hypertension and heart disease. He has published extensively on this subject with over 400 publications. He has authored or contributed to more than 30 books and numerous physician and patient education programs. He is editor-in chief of the Journal of Clinical Hypertension. Dr. Moser is also a member of the Board of The Third Avenue Value Funds and the Trudeau Institute. Dr. Moser holds a BA from Cornell University and an MD from Downstate University College of Medicine.

Robert E. Pollack, PhD, was elected a Director of the Company in January 1995. Dr. Pollack has been a Professor of Biological Sciences at Columbia University since 1978. In addition, from 1982 to 1989 he was Dean of Columbia College. Prior thereto he was Professor of Microbiology at the State University of New York School of Medicine at Stony Brook, Senior Scientist at Cold Spring Harbor Laboratory, Special NIH fellow at the Weizmann Institute in Israel, and NIH Fellow in the Department of Pathology at New York University School of Medicine. He is the author of more than one hundred research papers on the molecular biology of viral oncogenesis, a dozen articles in the popular press, and three books. He received a BA in physics from Columbia University and a PhD in biology from Brandeis University.

Benjamin T. Sporn has been legal counsel to the Company since 1990 and has served as Secretary of the Company since 1986, and was appointed Senior Vice President and General Counsel in February 1998. He was an attorney with AT&T from 1964 until December 1989 when he retired from AT&T as a General Attorney for Intellectual Property Matters. Mr. Sporn was a director of the Company from 1986 until 1994. He received a BSE degree from Rensselaer Polytechnic Institute and a JD degree from American University.

The Directors serve for a term of one year and until their successors are duly elected and qualified. Officers serve at the discretion of the Board of Directors, subject to the provisions of the employment agreements described below. Except for Mr. Paul Intlekofer, who is first cousin to Ms. Gail Montgomery, there are no family relationships among directors or executive officers.

#### Arrangements Regarding the Election of Directors

So long as Burns Philp & Company Limited owned at least 20% of the Company's outstanding common stock, BP was entitled to nominate one member for election to the Company's Board. On August 3, 2004, Burns Philp's ownership of the Company's common stock fell below 20%. BP has not nominated and is no longer entitled to nominate a member for election to the Company's Board. See Item 13. Certain Relationships and Related Transactions.

#### Director Compensation

Non-management Directors each receive a quarterly director's fee of \$1,800 and the Chairman of the Board receives a quarterly director's fee of \$3,600. Each non-management Director also receives \$500 for each meeting of the Board attended in person, \$250 for each meeting of the Board attended telephonically, and each received options to acquire 15,000 shares of Common Stock during the fiscal year ended June 30, 2004, at an exercise price of \$1.02. For the fiscal

year ending June 30, 2005, each non-management Director is expected to receive options to acquire 15,000 shares of Common Stock at the closing price on the date of grant.

### Committees of the Board of Directors

#### Audit Committee

The Company has a separately designated standing audit committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Serving on the Committee are P. George Benson, Warren D. Cooper and John H. Gutfreund. The Board of Directors has determined that it has an audit committee financial expert serving on the audit committee, John H. Gutfreund. Mr. Gutfreund is an independent director as defined in Item 7(d)(3)(iv) of Schedule 14A.

#### Compensation Committee

The Board of Directors has a Compensation Committee which consists of independent directors Audrey T. Cross, John H. Gutfreund, and Robert E. Pollack. The Compensation Committee held one meeting during the fiscal year ended June 30, 2004.

#### Compensation Committee Interlocks and Insider Participation

The Board of Directors determines executive compensation taking into consideration recommendations of the Compensation Committee. No member of the Company's Board of Directors is an executive officer of a company whose compensation committee or board of directors includes an executive officer of the Company.

#### Code of Ethics

The Company has adopted (i) Standards of Business Conduct ("Standards") and (ii) Business Conduct and Compliance Program ("Program") that includes its code of ethics. The Standards and Program are posted on the Company website: [www.nutrition21.com](http://www.nutrition21.com). After accessing the Company's website, click on Investor Relations and then on Shareholder Information. Any amendments or waivers will be posted on the Company's website.

#### Compliance with Section 16(a) of the Securities Exchange Act of 1934

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's officers and directors, and persons who own more than ten percent of a registered class of the Company's equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission. Officers, directors and greater than ten-percent shareholders are required by SEC regulation to furnish the Company with copies of all Section 16(a) forms they file.

Based solely on review of the copies of such forms furnished to the Company, or written representations that no filings were required, the Company believes that during the period from July 1, 2003 through June 30, 2004, all Section 16(a) filing requirements applicable to its officers, directors and greater than ten-percent beneficial owners were complied with.

## Item 11. EXECUTIVE COMPENSATION

The following table sets forth the compensation paid or accrued by the Company during the periods indicated for (i) the chief executive officer during fiscal year 2004 and (ii) certain other persons that served as executive officers in fiscal year 2004 whose total annual salary and bonus was in excess of \$100,000.

SUMMARY COMPENSATION TABLE (1)(2)

Name and Principal Position	Annual Compensation			Long-Term Compensation	All Other Compensation
	Period	Salary (\$)	Bonus (\$)	Securities Underlying Options/SARs (#)	(\$)
Gail Montgomery, President, Chief Executive Officer and Director	7/1/01 – 6/30/02	275,000		500,000	
	7/1/02 – 6/30/03	275,000		1,175,000	
	7/1/03 – 6/30/04	300,000 (4)			
Paul Intlekofer, Chief Financial Officer and Senior Vice President, Corporate Development	7/1/02 – 6/30/03	190,731		1,050,000	37,500 (3)
	7/1/03 – 6/30/04	219,135			
Benjamin T. Sporn, Senior Vice President, General Counsel and Secretary	7/1/01 – 6/30/02	207,500			
	7/1/02 – 6/30/03	207,500		225,000	
	7/1/03 – 6/30/04	194,808			

(1) The above compensation does not include the use of an automobile and other personal benefits, the total value of which do not exceed as to any named officer or director, the lesser of \$50,000 or 10% of such person's annual salary and bonus.

(2) Pursuant to the regulations promulgated by the Securities and Exchange Commission (the "Commission"), the table omits a number of columns reserved for types of compensation not applicable to the Company.

(3) Fees earned in a consulting capacity during fiscal year 2003.

(4) Includes \$25,000 of deferred compensation.

None of the individuals listed above received any long-term incentive plan awards during the fiscal year.

## Employment and Consulting Agreements

The Company has entered into a three-year employment agreement with Gail Montgomery as President and Chief Executive Officer, effective as of September 1, 2002. The agreement provides for an annual salary of \$275,000, \$300,000, and \$325,000 in the successive years under the agreement, and for performance bonuses based on achieving defined revenue targets. Ms. Montgomery is also entitled to additional payments equal to one year's salary plus an additional month of salary for defined years of service, if her employment is terminated without cause before the agreement expires, or if the Company fails to offer to enter into a new one-year agreement upon expiration. If Ms. Montgomery's employment is terminated or she resigns within six months after a change of control (as defined) the Company will pay to her 2.99 times her annual salary and previous year's bonus plus certain gross-ups, but these payments will be reduced to the extent necessary to prevent the application of Section 280G of the Internal Revenue Code.

Effective as of September 16, 2002 the Company entered into a three-year employment agreement with Paul Intlekofer, who has served as Chief Financial Officer and Senior Vice President, Corporate Development since January 17, 2003. The agreement provides for an annual salary of \$200,000, \$225,000, and \$250,000 in the successive years under the agreement, and for performance bonuses based on achieving defined revenue targets. Mr. Intlekofer is also entitled to additional payments equal to one year's salary, if his employment is terminated without cause before the agreement expires. If Mr. Intlekofer's employment is terminated or he resigns within six months after a change of control (as defined) the Company will pay to him 2.99 times his annual salary and previous year's bonus plus certain gross-ups, but these payments will be reduced to the extent necessary to prevent the application of Section 280G of the Internal Revenue Code.

The Company entered into a four-year agreement with Benjamin Sporn effective, September 1, 2002, which provides for his services as Senior Vice President, General Counsel, and Secretary as an employee during the first two years of the term, and as General Counsel as a consultant during the balance of the term. Mr. Sporn's salary and fees will be \$207,500, \$225,000, \$150,000 and \$100,000 in successive years under the agreement, plus performance bonuses based on achieving defined revenue targets. Mr. Sporn is also entitled to additional payments equal to two years' salary if his employment is terminated without cause before the agreement expires. If Mr. Sporn's employment is terminated or he resigns within six months after a change of control (as defined) the Company will pay to him 2.99 times his annual salary and previous year's bonus plus certain gross-ups, but these payments will be reduced to the extent necessary to prevent the application of Section 280G of the Internal Revenue Code.

The following tables set forth information with regard to options granted during the fiscal year (i) to the Company's Chief Executive Officer, and (ii) to other officers of the Company named in the Summary Compensation Table.

**OPTION/SAR GRANTS IN LAST FISCAL YEAR**

Individual Grants					Potential Realizable Value At Assumed Annual Rates Of Stock Price Appreciation For Option Term	
Name	Number Of Securities Underlying Options/SARs Granted (#)	Percent Of Total Options/SARs Granted To Employees In Fiscal Year	Exercise or Base Price (\$/Sh)	Expiration Date	5% (\$)	10% (\$)
Paul Intlekofer	0	0%	--	--	--	--
Gail Montgomery	0	0%	--	--	--	--
Benjamin T. Sporn	0	0%	--	--	--	--

**AGGREGATED OPTION/SAR EXERCISES IN LAST FISCAL YEAR  
AND FISCAL YEAR-END OPTION VALUES**

Individual Grants						
Name	Shares Acquired in Exercise (#)	Value realize d (\$)	Number of Unexercised Options/SARs at FY-End (#)		Value of Unexercised In-the- Money Options/SARs at FY- End	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Paul Intlekofer	0	0	293,333	766,667	\$68,967	\$186,333
Gail Montgomery	0	0	745,833	1,154,167	\$35,874	\$210,875
Benjamin T. Sporn	0	0	349,000	148,500	\$73,290	\$73,290

## Pension Plans

### Nutrition 21, Inc.

Eligible employees of the Company were entitled to participate in the Burns Philp Inc. Retirement Plan for Non-Bargaining Unit Employees, a non-contributory pension plan (the "Pension Plan") maintained by Burns Philp as long as Burns Philp maintained the Pension Plan and owned at least 20% of the Company's outstanding Common Stock. At June 30, 2004 and August 3, 2004, Burns Philp held approximately 20.44% and 19.29%, respectively, of the Company's outstanding Common Stock. Assuming retirement at age 65, the Pension Plan provides benefits equal to the greater of (a) 1.1% of the employee's final average earnings multiplied by the number of years of credited service plus 0.65% of the employee's final average earnings in excess of the average of the contribution and the benefit bases in effect under Section 230 of the Social Security Act for each year in the 35-year period ending with the year in which the employee attains the Social Security retirement age as calculated under Section 401(l)(5)(E) of the Code and Table I of IRS Notice 89-70, multiplied by the employee's years of credited service up to 35, minus any predecessor plan benefit in the case of an employee who participated in a predecessor plan or (b) \$24 multiplied by the number of years of credited service up to 25 years plus \$12 multiplied by the years of employment from 26-40 years, minus any predecessor plan benefit in the case of an employee who participated in a predecessor plan. The "final average earnings" are the average earnings during the five highest-paid consecutive calendar years within the last ten calendar years of credited service with the Company. Earnings include the salary and bonus listed in the summary compensation table. Earnings, which may be considered under the Pension Plan, are limited to \$205,000 in 2004 subject to annual cost of living adjustments as determined by the IRS.

On August 3, 2004, Burns Philp advised the Company that no further pension benefits will be earned for services performed or compensation paid on or after September 19, 2004. Service with the Company after September 19, 2004 will be considered solely for purposes of vesting and for determining eligibility for early retirement benefits.

The following table sets forth estimated annual benefits payable upon retirement, assuming retirement at age 65 in 2004, according to years of credited service and final average earnings. The benefits listed are not subject to any deduction for Social Security or other offset amounts.

### Years of Credited Service

Final average earnings	15	20	25	30	35
\$25,000	\$4,320	\$5,760	\$7,200	\$8,760	\$9,600
\$50,000	\$8,520	\$11,400	\$14,280	\$17,160	\$20,040
\$75,000	\$15,120	\$20,160	\$25,200	\$30,240	\$35,400
\$100,000	\$21,720	\$28,920	\$36,120	\$43,440	\$50,640
\$150,000	\$34,800	\$46,440	\$58,080	\$69,720	\$81,240
\$200,000 and up	\$47,880	\$63,960	\$79,920	\$95,880	\$111,960

Paul Intlekofer, Gail Montgomery, and Benjamin T. Sporn each have 1.8, 4.9, and 12 years, respectively, of credited service under the Pension Plan as of June 30, 2004, respectively.

**Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth, as of September 17, 2004, information regarding the beneficial ownership of the Company's Common Stock based upon the most recent information available to the Company for (i) each person known by the Company to own beneficially more than five (5%) percent of the Company's outstanding Common Stock, (ii) each of the Company's executive officers and directors and (iii) all executive officers and directors of the Company as a group. Unless otherwise indicated, each stockholder's address is c/o the Company, 4 Manhattanville Road, Purchase, New York 10577-2197.

**Shares Owned Beneficially and of Record (1)**

<b>Name and Address</b>	<b>No. of Shares</b>	<b>% of Class</b>
P. George Benson (2)	100,000	*
Warren D. Cooper (3)	40,000	*
Audrey T. Cross (4)	124,000	*
John H. Gutfreund (5)	120,000	*
Paul Intlekofer (6)	658,716	1.70
Gail Montgomery (7)	1,306,303	3.33
Marvin Moser (8)	185,000	*
Robert E. Pollack (3)	130,000	*
Benjamin T. Sporn (9)	505,625	1.31
Wyeth (10) 5 Giralda Farms Madison, NJ 07940	3,478,261	9.16
Burns Philp & Company Limited (11) 7 Bridge Street Sydney, NSW 2000, Australia	7,327,237	19.29
<input type="checkbox"/> All Executive Officers and Directors as a Group (9 persons) (12)	3,169,644	7.75

\* Less than 1%

(1) Unless otherwise indicated, each person has sole investment and voting power with respect to the shares indicated. For purposes of this table, a person or group or group of persons is deemed

to have "beneficial ownership" of any shares as of a given date, which such person has the right to acquire within 60 days after such date. For purposes of computing the percentage of outstanding shares held by each person or group of persons named above on a given date, any security which such person or group of persons has the right to acquire within 60 days after such date is deemed to be outstanding for the purposes of computing the percentage ownership of such person or persons, but is not deemed to be outstanding for the purpose of computing the percentage ownership of any other person.

(2) Includes 90,000 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(3) Consists of shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(4) Includes 120,000 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(5) Includes 70,000 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(6) Includes 626,666 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(7) Includes 1,181,666 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(8) Includes 175,000 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(9) Includes 471,500 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(10) Formerly American Home Products Corporation.

(11) Consists of shares owned by subsidiaries.

(12) Includes 2,904,832 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

## Equity Compensation Plan Information

The following table sets forth securities authorized for issuance under equity compensation plans as of June 30, 2004.

### Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,205,052	\$1.14	211,000
Equity compensation plans not approved by security holders	(1) 2,049,734 (2) 0 (3) 601,950	\$0.48  \$0.95	440,266 2,500,000
Total	5,856,736		3,151,266

(1) 2001 Stock Option Plan to provide non-executives, who render services to the Company additional incentives to advance the interests of the Company. Neither directors nor executive officers of the Company may be granted Stock Options under the Plan (Exhibit 10.70).

(2) 2002 Inducement Stock Option Plan to inducement an individual to be come an employee of the Company, and provide additional incentives to advance the interests of the Company. Neither directors nor executive officers of the Company may be granted Stock Options under the Plan (Exhibit 10.71).

(3) Warrants granted from time to time as an inducement to various persons or entities to enter into transactions with the Company.

## Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

On December 12, 1996, the Company completed the sale of its UK-based food ingredients subsidiary, Aplin & Barrett Limited ("A&B"), to Burns Philp & Company Limited ("BP") for \$13.5 million in cash and the return to the Company of 2.42 million shares of the Company's Common Stock held by BP. The sale included the Company's nisin-based food preservative business. In connection with the transaction, the Company and A&B entered into two License Agreements. Pursuant to the first License Agreement, the Company is exclusively licensed by A&B for the use of nisin generally in pharmaceutical products and animal healthcare products. Pursuant to the second License Agreement, A&B is exclusively licensed by the Company generally for the use of nisin as a food preservative and for food preservation. As long as BP owns at least 20% of the Company's outstanding common stock, BP is entitled to nominate one member for election to the Company's Board. BP has not nominated a member for election to the Company's Board. The amount of consideration for the sale was arrived at through arms-length negotiation and a fairness opinion was obtained. As of June 30, 2004, BP owned 7,763,837 shares of Common Stock, which amounted to 20.44% of the outstanding common stock. As of August 3, 2004, BP owned 7,327,237 shares of Common Stock, which amounted to 19.29% of the outstanding common stock, and is no longer entitled to nominate a director.

In October 1998, the Company issued 3,478,261 shares of Common Stock to Wyeth for \$4.0

million. At June 30, 2004, Wyeth held approximately 9.16% of the Company's outstanding Common Stock.

On July 1, 2000, the Company licensed its remaining rights to sell lysostaphin for research purposes, to Benjamin T. Sporn, its senior vice president, for \$300,000, payable in cash over a three-year period. Payment of the \$300,000 has been made. The price and other terms of the transaction were established through arms-length negotiations.

#### **Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

##### **Audit Committee Pre-Approval Policies and Procedures.**

The Audit Committee is directly and solely responsible for oversight, engagement and termination of any independent registered public accounting firm employed by the Company for the purpose of preparing or issuing an audit report or related work.

The Committee (i) meets with the independent registered public accounting firm prior to the audit and discusses the planning and staffing of the audit; (ii) approves in advance the engagement of the independent registered public accounting firm for all audit services and non-audit services and approves the fees and other terms of any such engagement; (iii) obtains periodically from the independent registered public accounting firm a formal written statement of the matters required to be discussed by Statement of Auditing Standards No. 61, as amended, and, in particular, describing all relationships between the auditor and the Company; and (iv) discusses with the independent registered public accounting firm any disclosed relationships or services that may impact auditor objectivity and independence.

Information Concerning Fees Paid to Independent Registered Public Accounting Firms for the fiscal years ended June 30, 2004 and 2003.

Set forth below is certain information concerning audit and related services rendered to the Company by J.H. Cohn LLP and Ernst & Young LLP for the fiscal years ended June 30, 2004 and 2003. As indicated below, in addition to reviewing financial statements, J.H. Cohn LLP and Ernst & Young LLP provided other services in the fiscal year ended June 30, 2004. The Audit Committee has determined that the provision of these other services is compatible with maintaining the independence of the firm.

*Audit Fees.* In the fiscal year ended June 30, 2004, J. H. Cohn LLP billed the Company \$95,000 for audit services. Ernst & Young LLP billed the Company for aggregate fees of approximately \$85,370 for audit services for the fiscal year ended June 30, 2003, up to their dismissal on July 31, 2003.

*Audit related fees.* In the fiscal year ended June 30, 2004, J.H. Cohn LLP billed the Company \$9,000 and Ernst & Young LLP billed the company \$12,500 for services related to registration on Form S-3.

*Tax Fees.* In the fiscal year ended June 30, 2004, J. H. Cohn LLP billed the Company \$20,000 for tax compliance services. Ernst & Young LLP billed the Company for aggregate fees of approximately \$25,975 for other services rendered in the fiscal year ended June 30, 2003, consisting primarily of tax compliance fees.

*All other fees.* None

## PART IV

### Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) 1. Financial Statements

The financial statements are listed in the Index to Consolidated Financial Statements on page F-1 and are filed as part of this annual report.

2. Financial Statement Schedules

The following financial statement schedule is included herein:

Schedule II – Valuation and Qualifying Accounts

All other schedules are not submitted because they are not applicable, not required, or because the information is included in the Consolidated Financial Statements.

3. Exhibits

The Index to Exhibits following the Signature Page indicates the Exhibits, which are being filed herewith, and the Exhibits, which are incorporated herein by reference.

(b) Reports on Form 8-K

The Company filed one Report on Form 8-K during the fiscal quarter ended June 30, 2004.

1. Report dated April 30, 2004 furnishing a copy of a press release of financial results for the fiscal quarter ended March 31, 2004.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NUTRITION 21, INC.

By: /s/ Gail Montgomery  
Gail Montgomery, President,  
CEO and Director

Dated: September 24, 2004

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below, as of September 24, 2004, by the following persons on behalf of Registrant and in the capacities indicated.

/s/ Gail Montgomery  
Gail Montgomery, President,  
CEO and Director

/s/ John H. Gutfreund  
John H. Gutfreund,  
Chairman of the Board

/s/ P. George Benson  
P. George Benson, Director

/s/ Warren D. Cooper  
Warren D. Cooper Director

/s/ Audrey T Cross  
Audrey T. Cross, Director

/s/ Marvin Moser  
Marvin Moser, Director

/s/ Robert E. Pollack  
Robert E. Pollack, Director

/s/ Paul Intlekofer  
Paul Intlekofer, Chief  
Financial Officer

## EXHIBITS

- 3.01 Certificate of Incorporation (1)
- 3.01a Certificate of Amendment to the Certificate of Incorporation (2)
- 3.01b Certificate of Amendment to the Certificate of Incorporation (3)
- 3.01c Certificate of Amendment to the Certificate of Incorporation (11)
- 3.01d Certificate of Amendment to the Certificate of Incorporation (11)
- 3.01e Certificate of Amendment to the Certificate of Incorporation (12)
- 3.02 Amended and Restated By-laws (2)
- 10.01 Form of Incentive Stock Option Plan (8)
- 10.02 Form of Non-qualified Stock Option Plan (8)
- 10.02a Form of 1989 Stock Option Plan (1)
- 10.02b Form of 1991 Stock Option Plan (1)
- 10.02c Form of 1998 Stock Option Plan (15)
- 10.24 Exclusive Option and Collaborative Research Agreement dated July 1, 1988 between the Company and the University of Maryland (4)
- 10.25 License and License Option Agreement dated December 15, 1988 between the Company and Babson Brothers Company (4)
- 10.36 Agreement, dated October 6, 1992 between the Company and PHRI (5)
- 10.47 Employment Agreement dated August 30, 1994 between the Company and Fredric D. Price, as amended and restated (6)
- 10.48 Lease dated as of February 7, 1995, between the Company and Keren Limited Partnership (7)
- 10.49 Share Purchase Agreement dated as of December 12, 1996, by and among Applied Microbiology, Inc., Aplin & Barrett Limited and Burns Philp (UK) plc. (9)
- 10.50 License Agreement dated as of December 12, 1996 between Licensee Applied Microbiology, Inc. and Licensor Aplin & Barrett Limited. (9)
- 10.51 License Agreement dated as of December 12, 1996 between Licensee Aplin & Barrett Limited and Licensor Applied Microbiology, Inc. (9)
- 10.52 Supply Agreement dated as of December 12, 1996 between Aplin & Barrett Limited and Applied Microbiology, Inc. (9)
- 10.53 Investors' Rights Agreement dated as of December 12, 1996 between Applied Microbiology, Inc. and Burns Philp Microbiology. Pty Limited. (9)

- 10.54 Revolving Loan and Security Agreement dated as of December 12, 1996 between Burns Philp Inc. as Lender and Applied Microbiology, Inc. as Borrower. (9)
- 10.55 Stock and Partnership Interest Purchase Agreement dated as of August 11, 1997, for the purchase of Nutrition 21. (10)
- 10.57 Sublease dated as of September 18, 1998, between the Company and Abitibi Consolidated Sales Corporation (12)
- 10.58 Stock Purchase Agreement dated as of September 17, 1998 between American Home Products Corporation and AMBI Inc. (13)\*
- 10.59 License, Option, and Marketing Agreement dated as of September 17, 1998 between American Home Products, acting through its Whitehall-Robins Healthcare division, and AMBI Inc. (13)\*
- 10.60 Amended and Restated Revolving Credit and Term Loan Agreement dated as of January 21, 1999 between State Street Bank & Trust Company as Lender and the Company and Nutrition 21 as Borrower. (14)
- 10.61 Agreement of Purchase and Sale of Assets made as of January 19, 1999 by and among Dean Radetsky and Cheryl Radetsky, Optimum Lifestyle, Inc. and AMBI Inc. (14)
- 10.62 Strategic Alliance Agreement dated as of August 13, 1999 between AMBI Inc. and QVC, Inc. (15)\*
- 10.63 Asset Purchase Agreement made as of December 30, 1999, by and between ImmuCell Corporation and AMBI Inc. (16)
- 10.64 License Agreement entered into as of August 2, 2000 between AMBI Inc. and Biosynexus Incorporated. (17)\*
- 10.65 License and Sublicense Agreement entered into as of August 2, 2000 between AMBI Inc. and Biosynexus Incorporated. (17)\*
- 10.66 Amendment effective as of June 30, 2000, to the Amended and Restated Revolving Credit and Term Loan Agreement dated as of January 21, 1999 between Citizens Bank of Massachusetts (successor in interest to loans originally made by State Street Bank & Trust Company) as Lender and the Company and Nutrition 21 as Borrower. (17)
- 10.67 Employment Agreement dated as of October 16, 2000 between AMBI Inc. and Gail Montgomery. (18)
- 10.68 Consulting Agreement entered into as of September 29, 2000 between AMBI Inc. and Fredrick D. Price. (19)
- 10.69 Amended and Restated By-laws, and Rights Agreement adopted September 12, 2002 (20)
- 10.70 Nutrition 21, Inc. 2001 Stock Option Plan. (21)

- 10.71 Nutrition 21, Inc. 2002 Inducement Stock Option Plan. (21)
- 10.72 Nutrition 21, Inc. Change of Control Policy adopted September 12, 2002. (21)
- 10.73 Employment Agreement entered into as of September 1, 2002 between Nutrition 21, Inc. and Gail Montgomery. (21)
- 10.74 Employment Agreement entered into as of August 5, 2002 between Nutrition 21, Inc. and Andrew Wertheim. (21)
- 10.75 Employment Agreement entered into as of September 1, 2002 between Nutrition 21, Inc. and Benjamin Sporn (21)
- 10.76 Employment Agreement entered into as of September 16, 2002 between Nutrition 21, Inc. and Paul Intlekofer (22)
- 23.1 Consent of J.H. Cohn LLP (23)
- 23.2 Consent of Ernst & Young LLP (23)
- 31.1 Certification of President and Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (23)
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (23)
- 32 Certification of President and Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (23)

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- (1) Incorporated by reference to the Company's Report on Form 10-K for 1991.
  - (2) Incorporated by reference to the Company's Report on Form 8-K dated September 4, 1992.
  - (3) Incorporated by reference to the Company's Registration Statement on Form S-8 dated August 8, 1996, file No. 333-09801.
  - (4) Incorporated by reference to the Company's Report on Form 10-K for 1988.
  - (5) Incorporated by reference to the Company's Report on Form 10-K for the fiscal period January 31, 1992 through August 31, 1992.
  - (6) Incorporated by reference to the Company's Report on Form 10-K for 1994.
  - (7) Incorporated by reference to the Company's Report on Form 10-K for 1995.
  - (8) Incorporated by reference to the Company's Registration Statement on Form S-1 originally filed April 15, 1986, file No. 33-4822.
  - (9) Incorporated by reference to the Company's Report on Form 8-K dated December 27, 1996.

- (10) Incorporated by reference to the Company's Report on Form 8-K dated August 25, 1997.
- (11) Incorporated by reference to the Company's Report on Form 10-K/A2 for 1997.
- (12) Incorporated by reference to the Company's Report on Form 10-K/A for 1998.
- (13) Incorporated by reference to the Company's Report on Form 10-Q for the quarter ended September 30, 1998.
- (14) Incorporated by reference to the Company's Report on Form 8-K dated February 3, 1999.
- (15) Incorporated by reference to the Company's Report on Form 10-K for 1999.
- (16) Incorporated by reference to ImmuCell Corporation's Report on Form 8-K dated January 13, 2000.
- (17) Incorporated by reference to the Company's Report on Form 10-K for 2000.
- (18) Incorporated by reference to the Company's Report on Form 10-Q for the quarter ended December 31, 2000.
- (19) Incorporated by reference to the Company's Report on Form 10-K for 2001.
- (20) Incorporated by reference to the Company's Report on Form 8-K dated September 18, 2002.
- (21) Incorporated by reference to the Company's Report on Form 10-K for 2002.
- (22) Incorporated by reference to the Company's Report on Form 10-K/A for 2003.
- (23) Filed herewith.

\* Subject to an order by the Securities and Exchange Commission granting confidential treatment. Specific portions of the document for which confidential treatment has been granted have been blacked out. Such portions have been filed separately with the Commission pursuant to the application for confidential treatment.

NUTRITION 21, INC.  
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS  
FILED WITH THE ANNUAL REPORT OF THE  
COMPANY ON FORM 10-K  
JUNE 30, 2004

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors  
Nutrition 21, Inc.

We have audited the accompanying consolidated balance sheets of Nutrition 21, Inc. and subsidiary as of June 30, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended. Our audit also included the 2004 and 2003 consolidated financial statement schedule listed in the Index in Item 15(a). These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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 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 consolidated financial position of Nutrition 21, Inc. and subsidiary as of June 30, 2004 and 2003, and their consolidated results of operations and cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the consolidated financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ J.H. Cohn LLP

Roseland, New Jersey  
August 25, 2004, except for the  
first paragraph of Note 14, which  
is as of September 3, 2004

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors  
Nutrition 21, Inc.

We have audited the consolidated statements of operations, stockholders' equity, and cash flows of Nutrition 21, Inc. (the "Company") for the year ended June 30, 2002. Our audit also included the related financial statement schedule for the year ended June 30, 2002 listed in the Index at Item 15(a)(2). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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 financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of operations and cash flows of Nutrition 21, Inc. for the year ended June 30, 2002, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule for the year ended June 30, 2002, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ ERNST & YOUNG LLP

Stamford, Connecticut  
August 16, 2002,  
except for the first paragraph of Note 8, Note 9 and  
the fourth and fifth paragraphs of Note 14, as to which the date is  
September 12, 2002

NUTRITION 21, INC.  
CONSOLIDATED BALANCE SHEETS  
(in thousands)

	June 30, <u>2004</u>	June 30, <u>2003</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$2,164	\$4,059
Short-term investments	2,000	--
Accounts receivable (less allowance for doubtful accounts and returns of \$10 in 2004 and \$430 in 2003)	1,342	1,140
Other receivables	257	1,100
Inventories	1,163	1,135
Prepaid expenses and other current assets	<u>221</u>	<u>196</u>
Total current assets	7,147	7,630
Property and equipment, net	314	479
Patents, trademarks and other intangibles (net of accumulated amortization of \$15,444 in 2004 and \$13,334 in 2003)	8,719	10,612
Other assets	<u>187</u>	<u>199</u>
<b>TOTAL ASSETS</b>	<b><u>\$16,367</u></b>	<b><u>\$18,920</u></b>

See accompanying notes.

NUTRITION 21, INC.  
CONSOLIDATED BALANCE SHEETS  
(in thousands, except share data)

	JUNE 30, <u>2004</u>	JUNE 30, <u>2003</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$3,687	\$3,456
Contingent payments payable	47	26
Preferred dividends payable	<u>--</u>	<u>2</u>
<b>TOTAL LIABILITIES</b>	<b><u>3,734</u></b>	<b><u>3,484</u></b>
<b>COMMITMENTS AND CONTINGENT LIABILITIES</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, \$0.01 par value, authorized 5,000,000 shares Series G convertible preferred, 1,769 shares issued, 188 shares outstanding at June 30, 2003	--	188
Common stock, \$0.005 par value, authorized 65,000,000 shares; 37,991,988 and 33,602,990 shares issued and outstanding at June 30, 2004 and 2003, respectively.	190	168
Additional paid-in capital	67,367	64,103
Accumulated deficit	<u>(54,924)</u>	<u>(49,023)</u>
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b><u>12,633</u></b>	<b><u>15,436</u></b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b><u>\$16,367</u></b>	<b><u>\$18,920</u></b>

See accompanying notes.

NUTRITION 21, INC.  
CONSOLIDATED STATEMENTS OF OPERATIONS  
(in thousands, except share and per share data)

	<u>YEAR ENDED JUNE 30,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Net sales	\$9,990	\$10,265	\$14,314
Other revenues	242	350	354
TOTAL REVENUES	10,232	10,615	14,668
Cost of goods sold	<u>2,119</u>	<u>4,129</u>	<u>4,344</u>
GROSS PROFIT	8,113	6,486	10,324
Selling, general & administrative expense	9,088	8,201	7,349
Research & development expense	2,382	2,232	1,017
Depreciation & amortization expense	2,497	2,691	2,619
Charges for impairment of intangibles	<u>---</u>	<u>4,443</u>	<u>7,128</u>
OPERATING (LOSS)	(5,854)	(11,081)	(7,789)
Interest income	46	64	94
Interest (expense)	(25)	(33)	(110)
Other income	<u>---</u>	<u>---</u>	<u>1,794</u>
(LOSS) BEFORE INCOME TAXES	(5,833)	(11,050)	(6,011)
Income taxes (benefit)	<u>68</u>	<u>(544)</u>	<u>---</u>
NET (LOSS)	<u>\$(5,901)</u>	<u>\$(10,506)</u>	<u>\$(6,011)</u>
Basic and diluted (loss) per common share	<u>\$(0.16)</u>	<u>\$(0.32)</u>	<u>\$(0.19)</u>
Weighted average number of common shares – basic and diluted	<u>36,767,826</u>	<u>33,309,371</u>	<u>32,621,918</u>

See accompanying notes.

NUTRITION 21, INC.  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands, except share data)

	Preferred Stock Series G	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Total
	Shares	Shares	\$	\$	\$	\$
Balance at June 30, 2001	941	32,342,818	63,196	(32,324)	--	31,974
Conversion of Series E preferred stock to common stock	--	155,605	193	--	--	194
Issuance of warrants	--	--	80	--	--	80
Preferred stock dividends declared	--	--	--	(51)	--	(51)
Premium on redemption of Series F preferred stock	--	--	--	(115)	--	(115)
Conversion of Series G preferred stock to common stock	(470)	686,232	467	--	--	--
Repurchase of common stock for treasury	--	(136,000)	--	--	(122)	(122)
Net loss for the year	--	--	--	(6,011)	--	(6,011)
Balance at June 30, 2002	471	33,048,655	63,936	(38,501)	(122)	25,949
Preferred stock dividends declared	--	--	--	(16)	--	(16)
Issuance of warrants	--	--	47	--	--	47
Conversion of Series G preferred stock to common stock	(283)	654,335	279	--	--	--
Repurchase of common stock for treasury	--	(100,000)	--	--	(38)	(38)
Retirement of treasury stock	--	--	(159)	--	160	--
Net loss for the year	--	--	--	(10,506)	--	(10,506)
Balance at June 30, 2003	188	33,602,990	64,103	(49,023)	--	15,436
Charge for stock appreciation rights	--	--	35	--	--	35
Exercise of stock options	--	10,000	6	--	--	6
Issuance of warrants to purchase 95,000 shares of common stock for services	--	--	52	--	--	52
Conversion of Series G preferred stock to common stock	(188)	316,498	186	--	--	--
Private placement of common stock	--	4,062,500	2,985	--	--	3,005
Net loss for the year	--	--	--	(5,901)	--	(5,901)
Balance at June 30, 2004	\$--	37,991,988	\$67,367	\$(54,924)	\$--	\$12,633

See accompanying notes.

NUTRITION 21, INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(in thousands)

	<u>YEAR ENDED JUNE 30,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Cash flows from operating activities:			
Net (loss)	\$(5,901)	\$(10,506)	\$ (6,011)
Adjustments to reconcile net (loss) to net cash (used in)/provided by operating activities:			
Depreciation and amortization	2,497	2,691	2,619
Impairment write-off	--	4,443	7,128
Deferred taxes	--	--	(725)
(Gain) loss on disposal of equipment	--	7	(55)
Issuance of warrants for services	52	47	80
Charge for stock appreciation rights	35	--	--
Changes in operating assets and liabilities:			
Accounts receivable	(202)	1,079	1,744
Other receivables	843	(3)	710
Inventories	(28)	(60)	231
Prepaid expenses and other current assets	(25)	591	26
Other assets	12	21	96
Accounts payable and accrued expenses	<u>231</u>	<u>1,354</u>	<u>(1,391)</u>
Net cash (used in)/provided by operating activities	<u>(2,486)</u>	<u>(336)</u>	<u>4,452</u>
Cash flows from investing activities:			
Contingent payments for acquisitions	(143)	(135)	(2,770)
Purchases of property and equipment	(12)	(86)	(274)
Payments for patents and trademarks	(263)	(350)	(336)
Proceeds from sale of equipment	--	50	200
Redemption of investments available for sale	3,500	1,000	--
Purchase of investments available for sale	<u>(5,500)</u>	<u>--</u>	<u>(1,000)</u>
Net cash (used in)/ provided by investing activities	<u>(2,418)</u>	<u>479</u>	<u>(4,180)</u>
Cash flows from financing activities:			
Debt repayments	--	--	(1,125)
Purchase of common stock for treasury	--	(38)	(122)
Redemption of redeemable preferred stock	--	--	(345)
Proceeds from stock option exercises	6	--	--
Preferred stock dividends paid	(2)	(20)	(61)
Net proceeds from private placement	<u>3,005</u>	<u>--</u>	<u>--</u>
Net cash provided by/(used in) financing activities	<u>3,009</u>	<u>(58)</u>	<u>(1,653)</u>
Net (decrease) increase in cash and cash equivalents	(1,895)	85	(1,381)
Cash and cash equivalents at beginning of year	<u>4,059</u>	<u>3,974</u>	<u>5,355</u>
Cash and cash equivalents at end of year	<u>\$2,164</u>	<u>\$4,059</u>	<u>\$3,974</u>

See accompanying notes.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1: NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a) Nature of Operations

Nutrition 21, Inc. and its subsidiaries (collectively, the "Company") is a nutritional bioscience company and the maker of chromium-based supplements with health benefits substantiated by clinical research. The Company markets Chromax chromium picolinate, which is the most studied form of the essential mineral chromium. The Company's operations related to the licensing of pharmaceutical products have become less material. Accordingly, effective in fiscal year 2004, the Company reports on the basis that it is one business segment.

b) Consolidation

The consolidated financial statements include the accounts of Nutrition 21, Inc, and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

c) Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

d) Cash Equivalents and Short-Term Investments

The Company considers all liquid interest-earning investments with a maturity of three months or less when acquired to be cash equivalents. Investments with maturities beyond one year may be classified as short-term based on their highly liquid nature and because such marketable securities represent the investment in cash that is available for current operations. All short-term investments are classified as available for sale and are recorded at market value. Realized gains and losses are determined using the specific identification method. Unrealized gains and losses would be reflected in Accumulated Other Comprehensive Income, if material. Cash equivalents included in the accompanying financial statements include money market accounts, bank overnight investments and commercial paper.

e) Inventories

Inventories, which consist of finished goods, are carried at the lower of cost (on a first-in, first-out method) or estimated net realizable value.

f) Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is provided using the straight-line method over the related assets' estimated useful lives. The estimated useful lives are as follows:

Leasehold improvements	--	Term of lease
Furniture and fixtures	--	7 years
Machinery and equipment	--	5 to 7 years
Office equipment	--	3 to 5 years
Computer equipment	--	3 to 5 years

g) Patents and Trademarks

The Company capitalizes certain patent and trademark costs. Patent and trademark costs are amortized over their estimated useful lives, ranging from 3 to 15 years.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1: NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

h) Revenue Recognition

Sales revenue is recognized when title transfers, upon delivery at the customer site. There are no customer acceptance provisions to be met before the recognition of any product revenue. Only revenue where collectability of accounts receivable is probable is recognized. Other revenues are comprised primarily of license and royalty fees recognized as earned in accordance with agreements entered into by the Company when there is no further involvement required by the Company. The Company accrues for related product returns based on historical activity.

i) Research and Development

Research and development costs are expensed as incurred.

j) Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to the temporary differences between the financial statement carrying amounts of assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

k) Stock-based Compensation

The Company continues to account for employee stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees." Compensation cost for stock options, if any, is measured as the excess of the quoted market price of the Company's stock at the date of grant over the amount an employee must pay to acquire the stock.

Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation," established accounting and disclosure requirements using a fair-value method of accounting for stock-based employee compensation plans. The Company has elected to remain on its current method of accounting as described above, and has adopted the disclosure requirements of SFAS No. 123 and SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure".

The Company applies the intrinsic value method pursuant to APB Opinion No. 25 in accounting for its employee stock option plans and, accordingly, no compensation cost has been recognized in the consolidated financial statements for its employee stock options, which have an exercise price equal to the fair value of the stock on the date of the grant. Had the Company determined compensation cost based on the fair value at the grant date for its stock options under SFAS No. 123 and amortized such costs over the vesting period, the Company's net loss would have been increased to the pro forma amounts indicated below (in thousands, except per share data):

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1: NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

	<u>2004</u>	Year-ended June 30, <u>2003</u>	<u>2002</u>
Net (loss) as reported	\$(5,901)	\$(10,506)	\$(6,011)
Deduct: total stock-based employee compensation expense determined under fair value based method for all awards	<u>(25)</u>	<u>(256)</u>	<u>(383)</u>
Pro forma net (loss)	<u>\$(5,926)</u>	<u>\$(10,762)</u>	<u>\$(6,394)</u>
(Loss) per share			
Basic – as reported	\$(0.16)	\$(0.32)	\$(0.19)
Basic – pro forma	\$(0.16)	\$(0.32)	\$(0.20)
Diluted – as reported	\$(0.16)	\$(0.32)	\$(0.19)
Diluted – pro forma	\$(0.16)	\$(0.32)	\$(0.20)

l) Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed

The Company reviews long-lived tangible assets and certain intangible assets with definite useful lives for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

m) Recently Issued Accounting Standards

In May 2003, the FASB issued SFAS No. 150, "Accounting for Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150, establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. The Company believes this pronouncement will have no effect on its consolidated financial statements.

n) Advertising costs

Advertising costs are expensed as incurred. The amount charged to expense during fiscal years 2004, 2003 and 2002 was \$0.9 million, \$0.6 million and \$0.4 million, respectively.

o) Reclassifications

Certain reclassifications have been made to prior years' financial statement amounts to conform to the 2004 presentation.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2: SHORT-TERM INVESTMENTS

Short-term investments are as follows (in thousands):	June 30,	
	<u>2004</u>	<u>2003</u>
Available for sale:		
1.81% corporate bond, maturing 6/1/05	\$1,000	\$----
2.03% corporate bond, maturing 12/22/05	<u>1,000</u>	<u>-----</u>
TOTAL	<u>\$2,000</u>	<u>\$----</u>

The fair value of the short-term investments at June 30, 2004 approximates the carrying value of the investments.

Note 3: FINANCIAL INSTRUMENTS AND MAJOR CUSTOMERS

The fair value of cash and cash equivalents, short-term investments, accounts receivable and accounts payable approximate carrying amounts due to the short maturities of these instruments.

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. Concentrations of credit risk with respect to accounts receivable are limited as the Company performs on-going credit evaluations of its customers and maintains credit insurance on customers' balances. On a periodic basis, the Company evaluates its accounts receivable and establishes an allowance for doubtful accounts, based on a history of past write-offs and collections and current credit considerations. Management does not believe that significant credit risk exists at June 30, 2004. The Company places its cash primarily in market interest rate accounts, overnight investments and short-term investments. The Company had \$0.4 million in overnight investments and \$1.8 million invested in mutual money market funds at June 30, 2004.

The Company sells its products to customers in the Americas. The Company performs ongoing credit evaluations of its customer's financial condition and limits the amount of credit extended as deemed appropriate, but generally requires no collateral. The Company maintains reserves for credit losses based on past write-offs, collections and current credit evaluations, and, to date, such losses have been within management's expectations.

In fiscal year 2004 and fiscal year 2003, two customers accounted for approximately 35% and 27% of net sales, respectively. For fiscal year 2002, one customer accounted for 28% of net sales. In addition, three customers accounted for 57% of accounts receivable, net at June 30, 2004, while two customers accounted for 40% of accounts receivable, net at June 30, 2003.

Note 4: RELATED PARTY TRANSACTIONS

A former officer's employment with the Company terminated on September 29, 2000. Effective as of such date, the Company entered into a consulting agreement with the former officer. The agreement was for the period from October 1, 2000 through June 30, 2004, and provided for payment of \$206,250 for the period from October 1, 2000 through June 30, 2001, and a fee at an annual rate of \$100,000 thereafter. All of the former officer's stock options (900,000 shares) became fully vested and became exercisable until June 30, 2004. As of June 30, 2004, no further payments are required, and all stock options have expired.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 5: PROPERTY AND EQUIPMENT, NET

The components of property and equipment, net, at June 30, 2004 and 2003 are as follows (in thousands):

	<u>2004</u>	<u>2003</u>
Furniture and fixtures	\$422	\$422
Machinery and equipment	135	135
Office equipment & leasehold improvements	542	542
Computer equipment	778	766
	1,877	1,865
Less: accumulated depreciation and amortization	<u>(1,563)</u>	<u>(1,386)</u>
Property and equipment, net	<u>\$314</u>	<u>\$479</u>

Note 6: PATENTS AND TRADEMARKS, NET

During fiscal years 2004, 2003 and 2002, changes in intangible assets relate to the investment of \$0.2 million, \$0.5 million and \$1.0 million, respectively, in existing patents, which will be amortized over the remaining life of the patents, as well as in fiscal year 2003, a \$4.4 million impairment charge relating to the discontinuance of the Lite Bites product line. No significant residual value is estimated for these intangible assets. Intangible asset amortization expense was \$2.3 million for fiscal year 2004, \$2.5 million for fiscal year 2003 and \$2.4 million for fiscal year 2002. The components of intangible assets were as follows (in thousands):

	June 30,			
	<u>2004</u>		<u>2003</u>	
	Gross Carrying <u>Amount</u>	Accumulated <u>Amortization</u>	Gross Carrying <u>Amount</u>	Accumulated <u>Amortization</u>
Patents and licenses	\$8,468	\$(7,246)	\$8,659	\$(5,958)
Trademarks, trade names and other	<u>15,695</u>	<u>(8,198)</u>	<u>15,287</u>	<u>(7,376)</u>
Intangible assets	<u>\$24,163</u>	<u>\$(15,444)</u>	<u>\$23,946</u>	<u>\$(13,334)</u>

Amortization expense for the net carrying amount of intangible assets at June 30, 2004 is estimated to be approximately \$2.1 million in fiscal years 2005 through 2008, respectively.

Note 7: ACCOUNTS PAYABLE AND ACCRUED EXPENSES

The following items are included in accounts payable and accrued expenses at June 30, 2004 and 2003 (in thousands):

	<u>2004</u>	<u>2003</u>
Accounts payable	\$1,130	\$1,903
Consulting and professional fees payable	172	109
Accrued compensation and related expense	302	160
Accrued termination expense	1,069	--
Other accrued expenses	<u>1,014</u>	<u>1,284</u>
	<u>\$3,687</u>	<u>\$3,456</u>

Note 8: STOCKHOLDERS' EQUITY

Inducement Plan

The Company adopted a 2002 Inducement Stock Option Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of options to purchase shares of the Company's common stock to induce individuals to become employed by the Company. The aggregate number of shares of common stock, which may become subject to options shall not exceed 2,500,000.

Approximately 2,500,000 options remain available for grant under the Inducement Plan at June 30, 2004.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8: STOCKHOLDERS' EQUITY (continued)

Warrants

The Company, from time to time, issues warrants to purchase Common Stock to non-employees for services rendered. Warrants are granted to purchase the Company's Common Stock with exercise prices set at fair market value on the date of grant. The terms of the warrants vary depending on the circumstances, but generally expire in three to five years.

The Company had outstanding warrants for the purchase of its Common Stock as follows:

	Number of warrants	Exercise price per share
Outstanding at June 30, 2001	1,132,137	\$0.89-\$6.30
Issued	160,000	\$0.63-\$0.74
Exercised	--	--
Cancelled	<u>(482,137)</u>	\$1.25-\$6.30
Outstanding at June 30, 2002	810,000	\$0.63-\$3.65
Issued	105,000	\$0.40-\$0.57
Exercised	--	--
Cancelled	<u>(70,000)</u>	\$2.59-\$3.62
Outstanding at June 30, 2003	845,000	\$0.40-\$3.65
Issued	216,950	\$0.62-\$1.11
Exercised	--	--
Cancelled	<u>(460,000)</u>	\$1.17-\$3.65
Outstanding at June 30, 2004	<u>601,950</u>	\$0.40-\$3.26

The warrants expire between 2003 and 2012. Certain of the warrants include anti-dilution clauses.

Warrants outstanding and exercisable at June 30, 2004 are as follows:

Range of Exercise Prices	Warrants Outstanding			Warrants Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.40 - \$0.89	400,000	2.47	\$0.69	400,000	\$0.69
\$1.05 - \$3.26	<u>201,950</u>	3.47	\$1.46	<u>201,950</u>	\$1.46
	<u>601,950</u>			<u>601,950</u>	

The Company recorded compensation expense associated with the issuance of warrants to third parties of \$52 thousand, \$47 thousand and \$80 thousand during fiscal years 2004, 2003 and 2002, respectively.

Options

In addition to the Inducement Plan, the Company had adopted five other Stock Option Plans ("Plans") whereby options to purchase an aggregate of 8,750,000 shares of the Company's common stock may be granted to employees, consultants and others who render services to the Company. The exercise price per share for the options granted under these Plans may not be less than the fair value of the Company's Common Stock on the date of grant. The options issuable pursuant to the Plans expire between 2004 and 2011. Approximately 651,000 options remain available for grant under these Plans at June 30, 2004.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8: STOCKHOLDERS' EQUITY (continued)

A summary of stock option activity related to the Company's stock option plans is as follows:

	<u>Number of options</u>	<u>Exercise price per share</u>
Outstanding at June 30, 2001	2,952,099	\$0.81 - \$7.56
Issued	1,230,000	\$0.55 - \$1.23
Exercised	--	
Cancelled	<u>(542,110)</u>	\$0.69 - \$7.56
Outstanding at June 30, 2002	3,639,989	\$0.55 - \$5.63
Issued	3,466,000	\$0.31 - \$0.71
Exercised	--	
Cancelled	<u>(591,987)</u>	\$0.37 - \$3.50
Outstanding at June 30, 2003	6,514,002	\$0.31 - \$5.63
Issued	632,400	\$0.54 - \$1.02
Exercised	(10,000)	\$0.76 - \$1.03
Cancelled	<u>(1,881,616)</u>	\$0.38 - \$5.19
Outstanding at June 30, 2004	<u>5,254,786</u>	\$0.31 - \$5.63

Each of these options is entitled to one share of common stock. Stock options generally vest ratably over several years from the date of grant and expire within ten years from the date of vesting.

Options outstanding and exercisable at June 30, 2004 are as follows:

Range of Exercise Prices	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.31 - \$0.94	3,600,234	8.26	\$0.49	1,181,242	\$0.54
\$1.00 - \$1.44	1,043,352	6.89	\$1.18	848,649	\$1.19
\$1.50 - \$2.94	421,200	3.92	\$2.23	370,700	\$2.27
\$3.00 - \$5.63	<u>190,000</u>	2.61	\$3.66	<u>183,600</u>	\$3.50
	<u>5,254,786</u>			<u>2,584,191</u>	

The per share weighted-average fair value of stock options granted during fiscal years 2004, 2003 and 2002 was \$0.25, \$0.06 and \$0.15, respectively, on the date of grant using the Black Scholes option-pricing model with the following weighted-average assumptions:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Risk-free interest rate	2.3%	2.2%	3.8%
Expected life-years	2.5	2.5	2.0
Expected volatility	125.5%	45.4%	45.6%
Expected dividend yield	--	--	--

Note 9: SHAREHOLDER RIGHTS PLAN

The Company adopted a Shareholder Rights Plan on September 12, 2002. Under this plan, the Company distributed, as a dividend, one preferred share purchase right for each share of Common Stock of the Company held by stockholders of record as of the close of business on September 25, 2002. The Rights Plan is designed to deter coercive takeover tactics, including the accumulation of shares in the open market or through private transactions, and to prevent an acquirer from gaining control of the Company without offering a fair price to all of the Company's stockholders. The Rights will expire on September 11, 2012.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Each Right entitles stockholders to buy one one-thousandth of a share of newly created Series H Participating Preferred Stock of the Company for \$3.00 per share. Each one one-thousandth of a share of the Preferred Stock is designed to be the functional equivalent of one share of Common Stock. The Rights will be exercisable only if a person or group acquires beneficial ownership of 15% or more of the Company's Common Stock (30% in the case of a person or group that is currently a 15% holder) or commences a tender or exchange offer upon consummation of which such person or group would beneficially own 15% or more the Company's Common Stock.

If any person or group (an "Acquiring Person") becomes the beneficial owner of 15% or more of the Company's Common Stock (30% in the case of a person that is currently a 15% holder), then (1) the Rights become exercisable for Common Stock instead of Preferred Stock, (2) the Rights held by the Acquiring Person and certain affiliated parties become void, and (3) the Rights held by others are converted into the right to acquire, at the purchase price specified in the Right, shares of Common Stock of the Company having a value equal to twice such purchase price. The Company will generally be entitled to redeem the Rights, at \$.001 per right, until 10 days (subject to extension) following a public announcement that an Acquiring Person has acquired a 15 % position.

Note 10: (LOSS) PER SHARE

The following table sets forth the computation of basic and diluted ( loss) per share for the periods indicated.

	<u>2004</u>	<u>Year ended June 30,</u> <u>2003</u>	<u>2002</u>
Basic and diluted (loss) per share:			
Net (loss)	\$(5,901)	\$(10,506)	\$(6,011)
Less: Dividends on preferred shares	--	(16)	(51)
Premium on redemption of preferred stock	--	--	(115)
(Loss) applicable to common stockholders	<u>\$(5,901)</u>	<u>\$(10,522)</u>	<u>\$(6,177)</u>
Weighted average shares	<u>36,767,826</u>	<u>33,309,371</u>	<u>32,621,918</u>
Basic and diluted (loss) per share	<u>\$(0.16)</u>	<u>\$(0.32)</u>	<u>\$(0.19)</u>

Diluted (loss) per share for the fiscal years ended June 30, 2003 and 2002, does not reflect the incremental shares from the assumed conversion of preferred stock, options and warrants (505,693 and 396,586 shares, respectively) as the effect of such inclusion would be anti-dilutive.

Note 11: GOODWILL

The Company adopted SFAS No. 142 effective July 1, 2001. Under SFAS No. 142, goodwill is no longer amortized but reviewed for impairment annually, or more frequently if certain indicators arise. The Company was required to complete the initial step of a transitional impairment test within six months of adoption of SFAS No. 142 and to complete the final step of the transitional impairment test by the end of the fiscal year. The initial step was completed in the first quarter of fiscal 2002. In addition, the Company assesses the impairment of identifiable intangible assets and goodwill whenever events or changes in circumstances indicate that the carrying value of the relevant assets may not be recoverable. Management's judgment regarding the existence of impairment is based on factors such as significant changes in the manner or the use of acquired assets or the Company's overall business strategy; significant negative industry or economic trends; significant declines in the Company's stock price for a sustained period and the Company's market capitalization relative to book value. Upon adoption, goodwill in the amount of \$4.1 million which was included in patents and trademarks since acquisition (although accounted for separately by the Company and included therein because of its estimated economic life) was reclassified in the accompanying balance sheets in accordance with the requirements of SFAS No. 142. Due to declining market conditions, as well as a change in business strategy, it was determined that a \$7.1 million impairment charge was warranted in fiscal year 2002. The Company used a discounted cash flow analysis for purposes of estimating the fair value of its reporting unit.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 12: PENSION PLAN

Eligible employees of the Company are entitled to participate in the Burns Philp Inc. Retirement Plan for Non-Bargaining Union Employees (the "Pension Plan"), a defined benefit pension plan, as long as Burn Philp maintains the Pension Plan and owns at least 20% of the Company's outstanding Common Stock. At June 30, 2004, Burns Philp held approximately 20% of the Company's outstanding Common Stock.

During fiscal years 2004, 2003, and 2002, the Company made contributions to the Pension Plan of \$239 thousand, \$131 thousand and \$106 thousand, respectively. As of August 3, 2004, Burns Philp's ownership of the Company's outstanding common stock fell below 20%. Burns Philp has notified the Company that no further pension benefits will be earned for services performed or compensation paid on or after September 19, 2004. Service with the Company after September 19, 2004 will be considered solely for purposes of vesting and for determining eligibility for early retirement benefits.

Note 13: INCOME TAXES

The provisions for income taxes for the fiscal years ended June 30, 2004, 2003 and 2002 consist of the following (in thousands):

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Current	\$68	\$(1,182)	\$725
Deferred	<u>--</u>	<u>638</u>	<u>(725)</u>
	<u>\$68</u>	<u>\$(544)</u>	<u>\$ ---</u>

Income taxes attributed to pre-tax ( loss) income differed from the amounts computed by applying the US federal statutory tax rate to pre-tax income as a result of the following (in thousands):

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Income taxes at U.S. statutory rate	\$(1,983)	\$(3,757)	\$(2,044)
Increase/ (reduction) in income taxes resulting from:			
Change in valuation allowance	1,983	4,184	1,607
Goodwill book basis in excess of tax	--	--	263
State taxes, net of federal	68	(663)	(268)
Other items	<u>--</u>	<u>(308)</u>	<u>442</u>
	<u>\$ 68</u>	<u>\$(544)</u>	<u>\$ ---</u>

The tax effects of temporary differences that give rise to deferred taxes and deferred tax assets and deferred tax liabilities at June 30, 2004 and 2003 are presented below (in thousands):

	<u>2004</u>	<u>2003</u>
Deferred tax assets:		
Net operating loss carryforwards	\$4,392	\$2,920
Accrued expenses	833	580
Inventory reserve	2	95
Intangible and fixed assets	4,886	2,188
Other	<u>3</u>	<u>8</u>
Total gross deferred tax assets	10,116	5,791
Less valuation allowance	(10,116)	(5,791)
Net deferred tax assets	<u>\$ ---</u>	<u>\$ ---</u>

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 13: INCOME TAXES (continued)

At June 30, 2004, the Company has available, for federal and state income tax purposes, net operating loss carry forwards of approximately \$10.7 million and \$12.7 million, respectively, expiring through 2024. Ultimate utilization of such net operating loss carryforwards may be significantly curtailed if a significant change in ownership of the Company were to occur. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Note 14: COMMITMENTS AND CONTINGENT LIABILITIES

On September 3, 2004, QVC filed a suit against the Company alleging that QVC has the right to return product to the Company and receive a payment of \$551,715, and for \$5,706 for certain services QVC allegedly rendered to the Company. QVC's purchase orders provide QVC the right to return product, provided the requests for return are made within certain time periods. The Company has reviewed its records and believes that QVC's requests for return were not timely. The Company is unable to predict the outcome of this matter.

The Company and the Federal Trade Commission (FTC) are discussing whether the Company should have any liability for weight loss advertising claims that were made on QVC, Inc. for the Company's Lite Bites® products. On March 24, 2004, the FTC sued QVC in the U.S. District Court for the Eastern District of Pennsylvania for these claims and for claims made on QVC for other products. QVC has in the same lawsuit filed on April 14, 2004, Third-Party Complaints for damages against six parties including the Company (Third-Party Defendants). The FTC and the Third-Party Defendants have filed Motions to Strike QVC's Third-Party Complaints. The Company discontinued the Lite Bites product line in fiscal year 2003. Neither the FTC nor QVC has set forth an amount being sought as damages, nor can the Company estimate its exposure.

On March 19, 2003, Andrew Wertheim (a former Executive Officer) initiated an arbitration with the American Arbitration Association against the Company in connection with his termination of employment. On July 24, 2004, an arbitrator awarded Mr. Wertheim (1) damages of \$268,477 for salary and benefits, (2) \$708,750 related to stock options, and (3) interest of \$92,151 (see Note 7). The Company believes that the arbitrator's award is in error. Accordingly, on August 3, 2004, the Company filed an action in the United States District Court for the Southern District of New York against Mr. Wertheim seeking to vacate the arbitration award. On August 16, 2004, the Company filed a Motion to Vacate the part of the award that relates to the stock options, i.e. \$708,750 plus interest.

The Company entered into a three-year employment agreement with Gail Montgomery as President and Chief Executive Officer, effective as of September 1, 2002. The agreement provides for an annual salary of \$275,000, \$300,000, and \$325,000 in the successive years under the agreement, and for performance bonuses based on achieving defined revenue targets. Ms. Montgomery is also entitled to additional payments equal to one year's salary plus an additional month of salary for defined years of service, if her employment is terminated without cause before the agreement expires, or if the Company fails to offer to enter into a new one-year agreement upon expiration. If Ms. Montgomery's employment is terminated or she resigns within six months after a change of control (as defined) the Company will pay to her 2.99 times her annual salary and previous year's bonus plus certain gross-ups, but these payments will be reduced to the extent necessary to prevent the application of Section 280G of the Internal Revenue Code. The Company in July 2002 granted to Ms. Montgomery options to purchase an aggregate of 850,000 shares of common stock at \$0.39 per share, and 325,000 stock appreciation rights ("SAR") on the same general terms as the option grant, except that upon exercise of the SAR the Company will pay to her the SAR's in-the-money value in cash or common stock.

The Company entered into a four-year agreement with Benjamin Sporn effective as of September 1, 2002, which provides for his services as Senior Vice President, General Counsel, and Secretary as an employee during the first two years of the term and as General Counsel as a consultant during the balance of the term. Mr. Sporn's salary and fees will be \$207,500, \$225,000, \$150,000 and \$100,000 in successive years under the agreement, plus performance bonuses based on achieving defined revenue targets. Mr. Sporn is also entitled to additional payments equal to two years' salary if his employment is terminated without cause before the agreement expires. If Mr. Sporn's employment is terminated or he resigns within six months after a change of control (as defined) the Company will pay to him 2.99 times his annual salary and previous year's bonus plus certain gross-ups, but these payments will be reduced to the

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 14: COMMITMENTS AND CONTINGENT LIABILITIES (continued)

extent necessary to prevent the application of Section 280G of the Internal Revenue Code. The Company in July 2002 granted to Mr. Sporn options to purchase an aggregate of 225,000 shares of the Company's Common Stock at \$0.39 per share.

Effective as of September 16, 2002, the Company entered into a three-year employment agreement with Paul Intlekofer, who has served as Chief Financial Officer and Senior Vice President, Corporate Development since January 17, 2003. The agreement provides for an annual salary of \$200,000, \$225,000, and \$250,000 in the successive years under the agreement, and for performance bonuses based on achieving defined revenue targets. Mr. Intlekofer is also entitled to additional payments equal to one year's salary if his employment is terminated without cause before the agreement expires. If Mr. Intlekofer's employment is terminated or he resigns within six months after a change of control (as defined) the Company will pay to him 2.99 times his annual salary and previous year's bonus plus certain gross-ups, but these payments will be reduced to the extent necessary to prevent the application of Section 280G of the Internal Revenue Code. The Company, in accordance with the agreement, granted to Mr. Paul Intlekofer options to purchase an aggregate 550,000 shares of the Company's common stock at \$0.40 per share.

In October 1995, the Company entered into an exclusive license agreement whereby the Company received a license to sell a patented salt alternative in the United States. During the term of the license, the Company agreed to pay a royalty of 4.5% of net sales of the salt alternative. The Company is required to make royalty payments quarterly through 2007. In connection with this agreement, the Company recorded royalty expense of \$2 thousand for the fiscal year ended June 30, 2004; \$2 thousand for the fiscal year ended June 30, 2003 and \$0.2 million for the fiscal year ended June 30, 2002.

The Company has entered into various research and license agreements with certain universities to supplement the Company's research activities and to obtain for the Company rights to certain technology. The agreements generally require the Company to fund the research and to pay royalties based upon a percentage of product sales.

The Company leases certain office space in the United States. The lease expires in the year 2006. Rent expense under this operating lease was approximately \$0.4 million in fiscal year 2004, \$0.4 million in fiscal year 2003, and \$0.5 million in fiscal year 2002. Future non-cancelable minimum payments under this lease are as follows (in thousands):

<u>Fiscal Year</u>	<u>Amount</u>
2005	370
2006	<u>278</u>
Total	<u>\$648</u>

In connection with the Company's purchase agreement for Nutrition 21 on August 11, 1997, the Company made cash payments in fiscal years 2004, 2003 and 2002 of \$143 thousand, \$135 thousand and \$1.8 million, respectively. In fiscal year 2002, the Company paid \$1.0 million in satisfaction of the contingent payment requirement to the owners of Optimum Lifestyle, Inc.

Note 15: SUPPLEMENTAL CASH FLOW INFORMATION

	Year ended June 30,		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Supplemental disclosure of cash flow information (in thousands)			
Cash paid for interest	\$ --	\$ 33	\$ 62
Cash paid for income taxes	2	41	504
Supplemental schedule of non-cash financing activities:			
Obligation for Nutrition 21 contingent payment	21	26	369
Obligation for Lite Bites contingent payment	--	--	589
Issuance of common stock for Series G conversion	188	283	----

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 16: QUARTERLY FINANCIAL INFORMATION (unaudited)

<u>In thousands, except per share data</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter (a)</u>
<u>Fiscal Year 2004</u>				
Revenues	\$2,358	\$2,395	\$2,648	\$2,831
Gross Profit	1,795	1,813	2,197	2,308
(Loss) before income taxes	(1,013)	(1,248)	(1,020)	(2,552)
Net (Loss)	(1,013)	(1,248)	(1,020)	(2,620)
Net (Loss) per common share:				
Basic	\$(0.03)	\$(0.03)	\$(0.03)	\$(0.07)
Diluted	\$(0.03)	\$(0.03)	\$(0.03)	\$(0.07)
<u>Fiscal Year 2003</u>				
Revenues	\$3,315	\$2,334	\$3,132	\$1,834
Gross Profit	2,506	1,352	2,115	513
(Loss) before income taxes	(112)	(2,270)	(1,449)	(7,219)
Net (Loss)	(112)	(2,270)	(1,143)	(6,981)
Net (Loss) per common share:				
Basic	\$(0.00)	\$(0.07)	\$(0.03)	\$(0.22)
Diluted	\$(0.00)	\$(0.07)	\$(0.03)	\$(0.22)

(a) The fourth quarter of fiscal year 2003 includes \$4.4 million of non-cash charges for impairment of intangibles.

## Schedule II

NUTRITION 21, INC.  
VALUATION AND QUALIFYING ACCOUNTS

<u>Accounts</u>	<u>Balance</u> <u>Beginning of</u> <u>Year</u>	<u>Additions</u>		<u>Deductions</u>	<u>Balance</u> <u>End</u> <u>of Year</u>
(\$ in thousands)		<u>Charged to</u> <u>Cost and</u> <u>Expense</u>	<u>Charged to</u> <u>Other Accounts</u>		
Year ended June 30, 2004					
Allowance for Doubtful Accounts	430	(411)	--	(9)	10
Deferred Tax Valuation Allowance	5,791	1,983	2,342***	--	10,116
Allowance for returns and allowances	1,060	--	(190)	(354)	516*
Allowance for inventory obsolescence	237	--	--	(231)	6
Year ended June 30, 2003					
Allowance for Doubtful Accounts	19	--	411	--	430
Deferred Tax Valuation Allowance	1,607	4,184	--	--	5,791
Allowance for returns and allowances	140	--	920	--	1,060*
Allowance for inventory obsolescence	1	236	--	--	237
Year ended June 30, 2002					
Allowance for Doubtful Accounts	45	--	--	(26)	19
Deferred Tax Valuation Allowance	1,360	1,607	(1,360)**	--	1,607
Allowance for returns and allowances	117	--	23	0	140*
Allowance for inventory obsolescence	31	(30)	--	--	1

\*Included in accrued expenses in the consolidated balance sheets.

\*\*Reclassified to reflect a deferred tax liability on acquired amortizable intangibles basis differences.

\*\*\*Reclassification of deferred tax assets and related valuation allowance.

## CORPORATE INFORMATION

### Directors

**John H. Gutfreund**

Chairman of the Board  
Nutrition 21, Inc.  
Senior Managing Director,  
C. E. Unterberg, Towbin, and  
President, Gutfreund & Company, Inc.

**Gail Montgomery**

President and Chief Executive Officer  
Nutrition 21, Inc.

**P. George Benson, PhD**

Dean of Terry College of Business  
University of Georgia

**Warren D. Cooper, MD**

President, Coalescence Inc.

**Audrey T. Cross, PhD**

Associate Clinical Professor  
School of Public Health  
Columbia University

**Marvin Moser, MD**

Clinical Professor of Medicine  
Yale University School of Medicine

**Robert E. Pollack, PhD**

Professor of Biological Sciences and  
former Dean of Columbia College,  
Columbia University

### Officers

**Gail Montgomery**

President and Chief Executive Officer

**Paul Intlekofer**

Chief Financial Officer and Senior Vice President,  
Corporate Development

**Benjamin T. Sporn**

Senior Vice President, General Counsel and Secretary

### Corporate Headquarters

Nutrition 21, Inc.  
4 Manhattanville Road  
Purchase, New York 10577

### Stockholders' Inquiries

Inquiries regarding transfer requirements,  
lost certificates, and changes of address  
should be directed to the transfer agent.

### Transfer Agent and Registrar

American Stock Transfer & Trust Company  
59 Maiden Lane – Plaza Level  
New York, New York 10038

### Stock Listing

Nasdaq under symbol "NXXI"

### SEC Form 10-K

A copy of the Company's annual report to the  
Securities and Exchange Commission on Form 10-K  
is available without charge upon written request to  
the Investor Relations Department.

### Auditors

J. H. COHN LLP  
75 Eisenhower Parkway  
Roseland, New Jersey 07068