

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM ~~10-K~~ **ARIS**

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

For Fiscal Year ended June 30, 2005

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)



05068158

New York

(State or other jurisdiction of incorporation or organization)

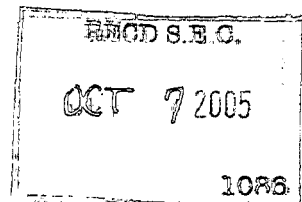
11-2653613

(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  
OCT 14 2005  
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  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

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

The aggregate market value of common stock held by non-affiliates of the registrant as of December 31, 2004 was \$28,116,016.

As of September 26, 2005, there were 38,405,413 shares of common stock outstanding.

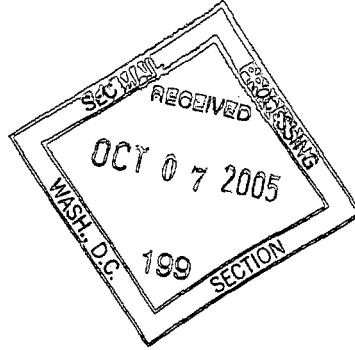
*[Handwritten mark]*

## FORM 10-K REPORT INDEX

10-K Part and Item No.		Page No.
PART I		
Item 1	Overview of the Business	3
Item 2	Properties	17
Item 3	Legal Proceedings	18
Item 4	Submission of Matters to a Vote of Security Holders	18
PART II		
Item 5	Market Price of Registrant's Common Equity and Related Stockholder Matters	20
Item 6	Selected Financial Data	21
Item 7	Management's Discussion and Analysis of Financial Condition and Results of Operations	21
Item 7A	Quantitative and Qualitative Disclosures About Market Risk	26
Item 8	Financial Statements and Supplementary Data	26
Item 9	Changes In and Disagreements with Accountants on Accounting and Financial Disclosure	26
Item 9A	Controls and Procedures	26
PART III		
Item 10	Directors and Executive Officers of the Registrant	28
Item 11	Executive Compensation	32
Item 12	Security Ownership of Certain Beneficial Owners and Management	34
Item 13	Certain Relationships and Related Transactions	36
Item 14	Principal Accounting Fees and Services	37
PART IV		
Item 15	Exhibits, Financial Statement Schedules	38



Essential for life™



Gail Montgomery  
President & CEO

Phone 914 701-4501  
Fax 914 696-0862  
Email [gmontgomery@nutrition21.com](mailto:gmontgomery@nutrition21.com)

September 30, 2005

Dear Shareholder:

For several years, we have focused primarily on the clinical and market development of our proprietary chromium formulations: Chromax® chromium picolinate, a premium chromium supplement, and Diachrome®, once-a-day nutritional support for people with diabetes. Nutrition Business Journal reports a 40% increase in the retail growth of the chromium mineral category during the three years ended last December. We think that Nutrition 21's aggressive investment in clinical studies and its promotion of the health outcomes associated with those studies have been the catalysts for this category growth.

Until fiscal 2005, our Chromax revenues were in major part derived from sales through our customers of chromium picolinate as part of multi-ingredient systems in weight loss supplements that have since been taken off the market. Starting in fiscal 2005, the sale of chromium as a single mineral supplement has driven our ingredient volume and revenue.

Eighty percent of stand-alone chromium mineral supplements are formulated with chromium picolinate. Nutrition 21 holds the patents for the essential nutritional uses for which chromium as chromium picolinate is sold, and is the only supplier that can legally license companies to market chromium picolinate for these patented uses in the US. This year researchers at Ohio State University demonstrated that chromium in the picolinate form is better absorbed than other commercially available forms of chromium.

In August of 2005, the US Food and Drug Administration (FDA) approved a qualified health claim suggesting that chromium picolinate plays a possible role in safely reducing the risk of insulin resistance and thereby reducing the risk of type 2 diabetes. The FDA's action opens the door for us to participate in a healthcare market that may be larger than that created by cholesterol lowering agents. According to the American Association of Clinical Endocrinologists, as many as one in three Americans may be insulin resistant. This market is still in its infancy; less than 3% of consumers are using chromium picolinate mineral supplements. There is a large and still untapped opportunity to create a premium brand of chromium picolinate to lead the growth of the chromium category.

Insulin is a hormone secreted by the pancreas, which helps the body utilize blood glucose (blood sugar). Insulin resistance occurs when the normal amount of insulin secreted by the pancreas is unable to unlock the receptors on the cell surface that need to open and allow the sugar in the blood to move into the cells of the body. In approximately one-third of the population that is insulin resistant, this underlying metabolic problem will lead to type 2 diabetes. The remaining two-thirds are at increased risk of heart disease, fatty liver disease, depression, polycystic ovarian syndrome and Alzheimer's. We expect that ongoing research will further confirm that low chromium status is a risk factor in many of these diseases associated with insulin resistance.

4 Manhattanville Road • Purchase, New York 10577 • Phone 914.701.4500  
Investor Relations 914.701.4545 • Fax 914.696.0860 • [www.Nutrition21.com](http://www.Nutrition21.com)

This new understanding of insulin resistance has created a marketing platform that we will use to launch Chromax chromium picolinate as a premium brand of chromium to consumers. Our goal over the next three years is to leverage our patent position, the FDA qualified health claim and publicity associated with the findings of government funded research programs to become the brand leader within the emerging chromium category, much like Caltrate is the brand leader in the calcium category.

Beginning in September 2005 we initiated a test market phase of our nationally televised direct-to-consumer Chromax media marketing campaign. Chromax will be positioned as an essential mineral that can not only prevent disease risk, but deliver measurable health benefits including: healthy blood sugar metabolism, improved energy, reduced carbohydrate cravings, and improved weight control. If the campaign is successful, we plan to roll the program out to retailers in calendar 2006. We are outsourcing the marketing services associated with these initiatives in order to minimize our financial risk and to maintain our flexibility. Our plan is to transition from a sole reliance on ingredient sales and to focus on brand sales as a key step in realizing the full value of our Company's intellectual property. We believe we now have all the necessary elements in place to do so.

Another primary focus this year has been to cultivate the US opportunity to introduce Diachrome into the oral anti-diabetic disease market through our relationship with our strategic partner, XLHealth. XLHealth is a disease management company that was awarded a government funded research grant to find new and more cost effective methods for caring for people with type 2 diabetes. There are an estimated 16 million people in the US with type 2 diabetes, and Medicare and Medicaid are caring for nearly half of them. The relationship between low chromium status and an increased incidence of diabetes and heart disease was confirmed this year by epidemiological researchers at Harvard and Johns Hopkins Universities. In addition, fourteen clinical trials show that chromium picolinate supplementation can improve glycemic control in people with and at risk for type 2 diabetes.

To capitalize on this nutrient-disease relationship, the Company three years ago decided to study and commercialize a premium chromium picolinate formulation to provide nutritional support for people with type 2 diabetes. As a result we invested in Diachrome, a patented combination of chromium picolinate and biotin. To position Diachrome for use in a competitive therapeutic market dominated by pharmaceutical agents, we needed to substantiate the benefits of Diachrome through gold standard research. We also wanted to demonstrate that the measurable health benefits of Diachrome could greatly alleviate the public health burden associated with diabetes care.

This year, we completed a pivotal 453 patient trial conducted in collaboration with XLHealth and showed that Diachrome improved blood sugar control, insulin resistance and cardiovascular risk factors in people with diabetes being treated with prescription drugs. Researchers at Thomas Jefferson University analyzed these results and translated the outcomes into an economic model suggesting that Diachrome use can save the US healthcare system billions of dollars.

In fiscal 2006, we will continue to publish and promote these findings to healthcare professionals and health policy makers with the goal of securing widespread adoption of Diachrome as a

medical nutrition therapy for people with type 2 diabetes. We plan to leverage our relationships with XLHealth and with Native American tribal leaders to initiate the rollout of our test market. Our first wave of educational materials and patient samples will be distributed to a targeted group of physicians in Texas, Tennessee and seven other states where we expect to secure distribution in independent pharmacies. We think that use of Diachrome on a regular basis among 1% of the US diabetes market could result in annual retail sales approaching \$200 million, a realistic goal.

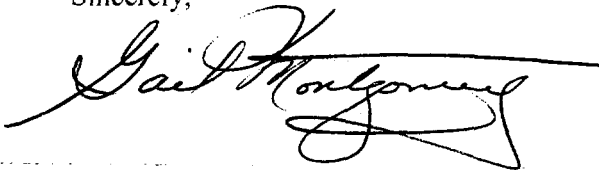
Our businesses require rigorous enforcement of our patents. In the latter half of fiscal 2005, contract manufacturers and marketers who previously purchased our ingredients began to test our willingness to monitor and enforce our patents. Partly as a result, in the last quarter of fiscal 2005 we experienced a fall off in chromium picolinate volume and associated revenues. In June 2005 we filed a patent infringement suit against GNC, and afterwards in the first quarter of fiscal 2006 we saw a correction in ingredient volume and revenues. The suit is scheduled for trial in December 2006. We are confident that the outcome will be favorable to us.

Going forward we will focus the majority of our spending on our consumer brands, but will continue to market chromium picolinate as an ingredient to functional food and beverage suppliers and for use in certain specialty supplements. We will also seek to develop international distribution partners who want to market our US consumer branded products abroad. We have signed on two international distributors and are holding discussions with others.

While we were pleased that during fiscal 2005 our high margin ingredient business continued to offset much of the risk and investment necessary to execute our brand strategy, we are most excited about developments that prepared us to move forward with our marketing plans in fiscal 2006. We successfully secured \$9.6 million in financing to fuel our transition. We firmly established the safety of our products with US and international regulatory bodies. We demonstrated the efficacy of our products. We built important relationships in the public health sector. We have engaged experienced marketing partners with a proven track record in successfully bringing new products to market. Now, in fiscal 2006, we look forward to testing, refining and implementing our marketing plans and working with our partners to build a new and exciting future for Nutrition 21 as the maker of Chromax and Diachrome.

Nutrition 21 has pioneered the use of pharmaceutical quality research to substantiate the benefits of its nutrition products in a healthcare market dominated by prescription medications. It is a strategy that has been time-consuming and costly, but necessary to differentiate our products from the myriad of nutrition products that lack medical credibility. We believe this scientific approach will yield a superior return on our investment. We thank our shareholders and our employees for their patience, effort and commitment to doing the right thing, the right way for the right opportunity: the opportunity to become a brand leader in an emerging healthcare market and to greatly lessen the public health burden associated with poor chromium nutrition and the risk of insulin resistance and type 2 diabetes.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail Montgomery". The signature is fluid and cursive, with a long horizontal line extending from the end of the name.

*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 37 patents for nutrition products, 26 of which are for chromium compounds and their uses. Nutrition 21's Chromax® chromium picolinate is a form of the essential mineral chromium developed by the USDA. It is used as an ingredient in many nutritional supplements.

The Company currently sells chromium picolinate and licenses the chromium picolinate to vitamin and supplement manufacturers and marketers for its patented uses in human and animal nutrition products at doses typically between 50-800 mcg under its Chromax trademark. Finished products that incorporate chromium picolinate are marketed to enable consumers to supplement 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. In December 2004, Congress passed an Appropriations bill that included Report Language that "chromium picolinate can restore normal glucose metabolism by enhancing insulin sensitivity," and encourages the National Center for Complementary and Alternative Medicine (NCCAM) to expand its chromium research.

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 for therapeutic applications in diabetes and other health conditions linked to insulin resistance. On August 25, 2005, the U.S. Food & Drug Administration (FDA), through its Qualified Health Claim (QHC) process, acknowledged there is limited but credible evidence to suggest that chromium picolinate may reduce the risk of insulin resistance, and therefore may possibly reduce the risk of type 2 diabetes. The FDA ruling is

the first QHC related to diabetes, and it is for chromium picolinate and not other forms of chromium. 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 of its most 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 U.S. and international institutions and government agencies, the Company's research objectives have been to strengthen the substantiation for FDA Qualified Health Claims of broad scope by continuing to:

- o Firmly establish the safety of Chromax chromium picolinate
- o Determine the mechanism of action of chromium picolinate in insulin mediated glucose metabolism
- o Confirm a relationship between low chromium status and an increased risk of diabetes and other conditions linked to insulin resistance
- o Use double-blind placebo-controlled trials to demonstrate the potential of its chromium product(s) to safely prevent, mitigate or treat diabetes
- o Explore chromium's potential role in mitigating or treating symptoms related to mental health issues, such as depression
- o Identify other opportunities to expand the therapeutic use of its chromium technology
- o 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

The Company plans to publicize the outcomes of these studies in order to reposition its products and increase the demand for chromium picolinate use in vitamin and supplement formulas. Additionally, Chromax chromium picolinate has been affirmed as Generally Recognized as Safe (GRAS) for use in nutritional bars and beverages. The Company is actively promoting its research findings, as well as the recent FDA pronouncement surrounding the safety of chromium picolinate to functional food manufacturers, including health and consumer product distributors in the U.S. as well as internationally. These are new market opportunities for the Company's products.

To date, the Company has not licensed the use of chromium picolinate as a consumer branded mineral supplement. To capitalize on the recent research outcomes and expansion of the chromium category, the Company is testing the market viability of its premium priced Chromax branded chromium picolinate mineral supplement. The Chromax brand will be targeted to consumers interested in improving their metabolic health to increase energy, fight weight gain and control carbohydrate cravings.

In addition to its core chromium research and development program, the Company is also commercializing Diachrome®, a 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, in December 2004 the Company completed a 453 patient, multi-center trial to confirm these findings. The Company is working with XLHealth to incorporate Diachrome into its treatment protocol. 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 in Texas and 20,000 Medicaid beneficiaries in Tennessee who are chronically ill with severe diabetes, congestive heart failure and cardiovascular disease. The Company also commissioned Thomas Jefferson University to translate the XLHealth research outcomes into potential healthcare cost savings if Diachrome were adopted broadly. Together these are key steps 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.

The Company holds patents for several other novel nutrition compounds and plans to expand its sales and 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 manufacture and distribute chromium picolinate as a stand-alone chromium supplement marketed either under their own private labels for their Vitamin, Mineral and Supplement lines such as Nature Made®, Natures Bounty®, or Sundown®, or under a store brand, such as CVS, Walgreens, or Wal-Mart's Spring Valley. The use of the Company's chromium picolinate, which includes a license from the Company under its patents, is required for all stand alone chromium picolinate products that are sold in the US for glucose control and its derivative benefits, including cholesterol control and improved body composition, the only established uses for chromium as chromium picolinate.

The calendar 2004 annual US retail market for stand-alone chromium mineral supplements is estimated to be \$119 million based on retail sales data provided by Nutrition Business Journal compared to \$106 million for calendar 2003 and \$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 chromium picolinate, while the rest are manufactured using chromium chloride, chromium polynicotinate or other forms of chromium.

The Company derives additional revenues from the sale and licensing of chromium picolinate to customers who incorporate it and other of the Company's ingredients into many other finished multi-ingredient nutritional supplement products. These include vitamin/mineral formulas, weight loss and sports nutrition supplements, bars, drink mixes, 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.

The Company's chromium picolinate is also sold into the animal feed market 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 purchase and 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 purchase and license grants to these customers a license under the Company's patents to sell the Company's 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, 2005, 2004 and 2003, respectively, ingredient sales of Chromax chromium picolinate accounted for more than 74%, 82%, and 74% of the Company's total revenues. In fiscal year 2005, two customers accounted for 34% of the Company's total revenues, while in fiscal year 2004, the same two customers accounted for 35% of the Company's total revenues. In fiscal year 2003, one customer accounted for 18% of the Company's total revenues.

The marketing opportunities for the Company's chromium picolinate, have been enhanced by recent safety announcements issued by the United States' Food & Drug Administration (FDA) and the United Kingdom's Food Standards Agency (FSA). 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.

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. BioReliance Corporation found Chromax chromium picolinate to be safe. This study was published in *Mutation Research, 2005*. Experts have advised that fruit fly studies do not predict results in humans.

#### The Company's Proposed Branded Products

Chromax®, chromium picolinate

To date, the Company has not licensed the use of chromium picolinate as a consumer branded mineral supplement. To capitalize on the recent research outcomes and expansion of the chromium category, the Company is testing the market viability of its premium priced Chromax branded chromium picolinate mineral supplement through direct response and subsequently retail distribution. The Chromax brand will be targeted to consumers interested in improving their metabolic health to: increase energy, fight weight gain and control carbohydrate cravings. The initial target market for Chromax will be woman age 35 to 55. The Company will further position Chromax for the pre-diabetes or insulin resistance market for both

men and women. Insulin resistance is an epidemic condition that dramatically increases risk for type 2 diabetes, coronary heart disease and stroke, estimated to affect one in three Americans; according to The American College of Endocrinology (ACE).

Diachrome®, chromium picolinate plus biotin

The Company is positioning 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. People with diabetes are known to have lower levels of chromium and biotin than healthy people. 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. Building on pre-clinical and this early clinical research, the Company 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 and lipid control in people with type 2 diabetes and/or have CVD risk factors. Together, the companies conducted a 90-day, 453 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 XLHealth study was completed in December 2004. The Company is working with XLHealth to incorporate Diachrome into its treatment protocol. Diachrome will be 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 in Texas and 20,000 Medicaid beneficiaries in Tennessee who are chronically ill with severe diabetes, congestive heart failure and cardiovascular disease. The Company also commissioned Thomas Jefferson University to translate the XLHealth research outcomes into potential healthcare cost savings if Diachrome were adopted broadly. This is a key element of 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. The Company plans a targeted direct-to-physician marketing and sampling program to managed diabetic populations. The Company also 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.

#### The Company's Pharmaceutical Licensing Opportunities for its Chromium Technologies

As part of its intellectual property portfolio, the Company owns or has exclusive licenses to a number of patents related to pharmaceutical applications alone or in combination with prescription drugs. Specifically, these patents relate to chromium's role in treating mental health conditions, such as depression and PMS/PMDD. The Company also has a patent pending related to chromium's role in mitigating the negative effects caused by drug induced insulin resistance. The Company intends to out-license the development and marketing of these pharmaceutical products to pharmaceutical companies.

## Pharmaceutical Products Licensed to Third Parties

In August 2000, the Company exclusively licensed to Biosynexus Incorporated 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 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”). During the period April 2000 through February 2002, the Company exclusively licensed to ImmuCell worldwide rights to develop and market new antibacterial drugs for animals using the Company’s nisin technology, as well as certain rights for nisin-based teat dips as a mastitis preventative. These licenses provide for milestone and royalty payments. In November 2004, in consideration of a \$1.0 million payment, the Company waived its rights to receive potential milestone and royalty payments for a majority of the licensed animal uses of nisin. There is a continuing royalty obligation upon commercial sale of skin and environmental sanitizers and teat dips for the prevention of mastitis.

## **Research and Development**

During the fiscal years ended June 30, 2005, 2004 and 2003, the Company spent approximately \$2.7 million, \$2.4 million, and \$2.2 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, cardiovascular health, and mental 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, as well as further differentiating chromium picolinate’s clinical effects versus other forms of chromium.

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 safety, efficacy and mechanism 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.

Studies in progress:

### Chromax

The Company has supplied its Chromax chromium picolinate to Griffin Hospital/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 its 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.

The Company supplied Chromax chromium picolinate to Children's Hospital Los Angeles for a clinical study entitled "*Evaluation of the Improvement in Glycemic Control, Blood Lipid Levels and Other Risk Factors After Daily Supplementation with Chromium Picolinate, in a Pediatric Population Diagnosed with Type 1 Diabetes Mellitus Who Are Overweight. A Randomized, Double-Blind, Placebo-Controlled Clinical Trial.*" This study is evaluating the effect of supplementation with chromium picolinate on blood glucose control, lipid profiles, body weight and BMI. This study will be the first to provide data on children with type 1 diabetes.

The Company supplied Chromax chromium picolinate to the Sansum Diabetes Research Institute for a clinical study entitled "*Treatment of PCOS in Adolescents Comparing Chromium Picolinate with Diet and Exercise to Diet and Exercise Alone.*" This study is evaluating the effect of supplementation with chromium picolinate on improving insulin sensitivity and reducing symptoms of polycystic ovary syndrome in adolescent females.

The Company supplied Chromax chromium picolinate to Pennington Biomedical Research Center for a clinical study entitled "*Effects of Chromium Picolinate on Food Intake, Satiety, and Eating Attitudes in Overweight Women with Food Cravings.*" This study is evaluating the effect of supplementation with chromium picolinate on food intake, food cravings, eating attitudes and satiety in healthy overweight and/or obese adult women who are determined to be carbohydrate cravers.

#### Diachrome

The Company has supplied its Diachrome product (Chromax chromium picolinate and biotin) and paid \$21,000 to date to conduct an extension phase to a clinical study 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 additional data on the longer-term effects (90 + 270 days) of Diachrome on diabetes risk factors, and is expected to reflect continued improvements in blood glucose control, beta cell function and insulin sensitivity. Any data that are positive should provide additional support for the use of Diachrome as a adjunctive nutritional therapy for people with diabetes.

## Studies Completed in 2005:

### Chromax

The Company gave a \$900,000 research grant to Comprehensive Neuroscience Inc. to conduct a clinical study entitled "*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.

The Company gave a \$30,000 research grant to Ohio State University to conduct a clinical study entitled "*Acute Comparison of Different Forms of Zinc and Chromium Supplements.*" The study was a single-blind trial of Chromax chromium picolinate compared to other forms of chromium in healthy women. Results from this study showed that chromium picolinate was better absorbed than the other forms of chromium tested.

### Diachrome

The Company has supplied its Diachrome product (Chromax chromium picolinate and biotin) and paid \$1,200,000 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.*" Results from this study show that 90 days of supplementation with Diachrome can help improve blood glucose control and reduce elevated cholesterol levels in people with poorly controlled diabetes.

## Presentations and Publications in 2005:

A paper on "*Absence of Toxic Effects in F344/N Rats and B6C3F1 Mice Following Subchronic Administration of Chromium Picolinate Monohydrate*" was published in Food Chemical Toxicology. This paper concluded that no compound-related changes in hematology and clinical chemistry parameters were observed. There were no histopathological lesions attributed to CPM in rats or mice.

A paper on "*Resistive Training and Chromium Picolinate: Effects on Inositols and Liver and Kidney Functions in Older Adults*" was published in International Journal of Sports Nutrition and Exercise Metabolism. This paper concluded that chromium picolinate is safe as dietary supplement.

A paper on "*Insulin Sensitizing Action of Chromium Picolinate in Various Experimental Models of Diabetes Mellitus*" was published in Journal of Trace Element and Medical Biology. This paper concluded that chromium picolinate significantly improves carbohydrate and lipid metabolism and suggests anti-diabetic action.

A scientific review paper on "*Role of Chromium in Human Health and in Diabetes*" was published in Diabetes Care. This paper concluded that chromium picolinate significantly reduces blood sugar levels and improves insulin sensitivity in type 2 diabetes.

A paper on "*Lower Toenail Chromium in Men with Diabetes and Cardiovascular Disease Compared with Healthy Men*" was published in Diabetes Care. This paper concluded that diabetic men with CVD have lower toenail chromium than healthy control subjects.

A paper on "*Chromium Supplementation Shortens QTc Interval Duration in Patients with Type 2 Diabetes Mellitus*" was published in American Heart Journal. This paper concluded that short-term chromium as chromium picolinate supplementation shortens QTc interval in patients with type 2 diabetes mellitus.

A paper on "*Effect of Chromium Supplementation on Blood Glucose and Lipid Levels in Type 2 Diabetes Mellitus Elderly Patients*" was published in the International Journal of Vitamin Nutrition Research. This paper concluded that chromium picolinate reduced postprandial blood glucose and coronary risk lipids and lipoproteins in elderly patients.

A paper on "*Effects of Acute Chromium Supplementation on Postprandial Metabolism in Healthy Young Men*" was published in the American College of Nutrition. This paper concluded that acute chromium supplementation showed an effect on postprandial glucose metabolism in most of the subjects.

A poster presentation entitled "*Improvement in Glycemic Control, Lipids and Insulin Sensitivity with the Combination of Chromium Picolinate and Biotin in Type 2 Diabetes Mellitus*" was given at the 65<sup>th</sup> Scientific Sessions of American Diabetes Association. This presentation showed beneficial effects of chromium picolinate and biotin combination (Diachrome) on lowering elevated glycosylated hemoglobin (HbA1c), hyperglycemia and dyslipidemia in people with type 2 diabetes.

A poster presentation entitled "*Effect of Chromium Picolinate on Body Composition, Insulin Sensitivity, and Glycemic Control in Subjects with Type 2 Diabetes*" was given at the 65<sup>th</sup> Scientific Sessions of American Diabetes Association. This presentation reported CrPic supplementation in subjects with type 2 diabetics significantly improves insulin sensitivity and glucose control. Further, CrPic supplementation significantly attenuated body weight gain and visceral fat accumulation compared to the placebo group.

A poster presentation entitled "*Effect of Chromium Picolinate and Biotin Combination on Glycosylated Hemoglobin and Plasma Glucose in Subjects with Type 2 Diabetes Mellitus with Baseline HbA1c  $\geq 10\%$* " was given at Endocrine Society Annual Meeting. This presentation reported reductions in glycosylated hemoglobin levels in poorly controlled type 2 diabetes.

A poster presentation entitled "*Effect of Chromium Picolinate and Biotin Combination on Coronary Risk Lipids and Lipoproteins in Subjects with non HDL -C ( $\geq 130$  mg/dL) in Type 2 Diabetes Mellitus*" was given at the American Heart Association, Council on Arteriosclerosis, Thrombosis and Vascular biology. This presentation reported beneficial effects of chromium picolinate and biotin combination (Diachrome) on improving coronary risk lipids and lipoproteins in people with type 2 diabetes.

A poster presentation entitled "*Comparison of Acute Absorption of Various Types of Chromium Supplement Complexes*" was given at a meeting of the Federation of American Societies for Experimental Biology. This presentation reported that chromium picolinate is better absorbed than other chromium complexes used for supplement purposes.

A poster presentation entitled "*Dietary Chromium Intake and Risk Factors in Moderately Obese Subjects with Type 2 Diabetes Mellitus*" was given at a meeting of the Federation of American Societies for Experimental Biology. This presentation showed dietary chromium intakes and its correlation with diabetes risk factors in type 2 diabetes.

A poster presentation entitled "*Effects of Chromium Picolinate and Biotin Supplementation on Urinary Chromium and Diabetes Risk Factors in Moderately Obese Subjects with Type 2 Diabetes Mellitus*" was given at a meeting of the Second World Congress on Insulin Resistance Syndrome. This presentation reported that there is a significant relationship between urinary chromium and diabetes risk factors.

A poster presentation entitled "*Effect of Chromium Picolinate and Biotin on Post Prandial Hyperglycemia in Moderately Obese Subjects with Type 2 Diabetes Mellitus*" was given at The North American

Association for the Study of Obesity. This presentation showed that chromium picolinate and biotin combination significantly reduced area under curve glucose and other lipid risk factors.

A poster presentation entitled "*Chromium Picolinate Does Not Produce Chromosome Damage in the In Vitro Mammalian Chromosome Aberration Test with CHO Cells*" was given at the Environmental Mutagen Society Annual Meeting. This presentation reported that chromium picolinate does not produce chromosome damage and aberration in Chinese hamster ovary cells.

A poster presentation entitled "*Lack of Mutagenicity of Chromium Picolinate in the CHO/HGPRT Mutation Assay: Results from Standard Tests and a Test with a 48-Hour Exposure Period*" was given at the Environmental Mutagen Society Annual Meeting. This presentation reported that CrPic (as Chromax®) was concluded to be non-mutagenic both in the standard CHO/HGPRT assay and in the test using a 48-hour exposure period.

A poster presentation entitled "*Evaluation of Safety in a Clinical Trial Studying the Effects of Chromium Picolinate on Atypical Depression*" was given at the Annual Meeting of the American College of Toxicology. This presentation showed that daily oral administration of 600 mcg Cr, as CrPic, is safe and well tolerated with no clinically meaningful differences in AEs, including sexual dysfunction and weight gain, or CIs as compared to placebo.

A presentation entitled "*Evaluation of the Genotoxicity and Potential Carcinogenicity of Chromium Picolinate*" was given at the Annual Meeting of the Center for Disease Control: The National Institute of Occupational Health. This presentation reported that chromium picolinate is not genotoxic.

Studies Completed in 2004:

#### Chromax

The Company gave a \$121,000 research grant to the University of Connecticut to conduct a clinical study entitled "*A Randomized, Double Blinded, Placebo Controlled, Parallel Arm Study to Evaluate the Effect of Chromium Picolinate Supplementation on Glycogen Resynthesis after Exercise*". This study was a double-blind placebo-controlled trial in healthy moderately overweight men, to evaluate if Chromax chromium picolinate could restore muscle glycogen levels after intense exercise. Results from this study are currently being evaluated.

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.

#### Diachrome

The Company has supplied its Diachrome product (Chromax chromium picolinate and biotin) and paid \$190,000 to conduct a clinical study that is entitled "*A Randomized, Double Blinded, Placebo Controlled, Parallel Arm, Study To Evaluate The Improvement In Glycemic Control After Daily Administration Of Chromium Picolinate And Biotin In Patients With Type 2 Diabetes Mellitus*." Results from this study show that 30 days of supplementation with Diachrome can help improve blood glucose control and reduce elevated cholesterol levels in people with poorly controlled diabetes.

#### 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 the 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:

### 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*.

### 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.

## 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 elected to seek FDA approval for health claims. On August 25, 2005, the FDA issued a favorable response, recognizing chromium picolinate as a safe nutritional supplement that may reduce the risk of insulin resistance and possibly type 2 diabetes. The FDA declined to permit other qualified health claims that were proposed by the Company. The FDA concluded:

*"One small study suggests that chromium picolinate may reduce the risk of insulin resistance, and therefore possibly may reduce the risk of type 2 diabetes. FDA concludes, however, that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain."*

The FDA also concluded that chromium picolinate is safe stating the following:

*"FDA concludes at this time, under the preliminary requirements of 21 CFR 101.14(b)(3)(ii), that the use of chromium picolinate in dietary supplements as described in the [approved] qualified health claims discussed in section IV is safe and lawful under the applicable provisions of the Act."*

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 37 issued US patents and 12 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, 26 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 use the Company's chromium picolinate and become licensed under 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.

In 2005, the Company initiated a patent infringement case against General Nutrition Corporation for infringement of three chromium method of use patents. The case is venued in the Eastern District of Texas, Tyler Division.

#### 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 consumer health branded business will confront many large established companies in a huge industry that serves the diabetes therapeutics 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. All of our suppliers are GMP (Good Manufacturing Practices) compliant as published by the U.S. Pharmacopeia for nutritional supplements as well as the proposed FDA GMPs for nutritional supplements. GMP is a system of procedures and documentation written or analytical, to assure our products contain the appropriate strength, quality, composition and purity to which it purports to have.

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, 2005, the Company had 34 full-time employees, of whom 2 were executive employees, 10 were administrative, 14 were engaged in marketing and sales, and 8 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 has maintained its corporate 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. On June 15, 2005, the Company extended the term of the lease of its corporate headquarters to March 15, 2009, at an annual lease rental of \$338,040, 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 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 damages of (1) \$269,000 for salary and benefits, (2) \$709,000 related to stock options, and (3) interest of \$92,000. On November 1, 2004, the United States District court for the Southern District of New York denied a motion by the Company to vacate the part of the award that relates to the stock options, i.e. \$709,000 plus interest. The Company appealed the decision of the District Court. On December 13, 2004, the Company posted \$1,225,000 as security with the Clerk of the District Court, pending final resolution of the 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 Company, in the same lawsuit, filed on March 4, 2005, a Third-Party Complaint for indemnity against Marvin Segel, its on-air spokesperson for Lite-Bite products. 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. The Company and QVC have agreed to settle this suit for a payment by the Company of \$390,000. The terms of the settlement agreement are being negotiated.

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, one patent infringement action is ongoing against General Nutrition Corporation for infringement of three chromium method of use patents. The case is venued in the Eastern District of Texas, Tyler Division. 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**

A Special Meeting of Shareholders of Nutrition 21, Inc. (the "Company") was held at 4 Manhattanville Road, Purchase, New York at 10:00 a.m. on June 28, 2005 and adjourned and continued on July 28, 2005. The purpose of the meeting was:

1. To adopt an amendment to the Certificate of Incorporation that would increase the number of the Company's authorized shares of common stock from 65,000,000 to 100,000,000.
2. To adopt a proposal that would remove price limits that were imposed on issuances and on anti-dilution provisions in connection with the Company's recent issuance of preferred stock.
3. To adopt a proposal to permit shares of common stock to be used for the payment of dividends on the preferred stock.
4. To adopt the Company's 2005 Stock Plan.

5. To transact such other business as may properly come before the meeting or any adjournments thereof.

Proposals 1, 2, 3 and 4 were passed by the votes indicated:

	<u>FOR</u>	<u>AGAINST</u>	<u>ABSTAIN</u>
Proposal 1	20,668,549	5,438,667	296,257
Proposal 2	13,802,188	5,634,234	181,803
Proposal 3	14,427,245	5,077,585	113,395
Proposal 4	14,169,138	5,210,023	239,064

## 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. In addition, as long as dividends on the Company's Series I Preferred Stock are unpaid, the Company is precluded from paying dividends on its Common Stock and any other equity securities.

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, 2003	\$1.66	\$0.40
December 31, 2003	\$1.25	\$0.65
March 31, 2004	\$1.03	\$0.53
June 30, 2004	\$1.31	\$0.50
September 30, 2004	\$1.00	\$0.29
December 31, 2004	\$1.40	\$0.71
March 31, 2005	\$1.38	\$0.80
June 30, 2005	\$1.35	\$0.45

As of September 16, 2005, there were approximately 475 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 Series H 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 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, then (1) the Rights become exercisable for Common Stock instead of Series H 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,				
	2005	2004	2003 <sup>(2)</sup>	2002 <sup>(1)</sup>	2001
Total Revenues	\$10,711	\$10,232	\$10,615	\$14,668	\$23,252
Gross Profit	8,242	8,113	6,486	10,324	17,036
Operating Loss	(6,619)	(5,854)	(11,081)	(7,789)	(955)
(Loss) Income Before Taxes (Benefit)	(7,025)	(5,833)	(11,050)	(6,011)	1,400
Income Taxes Provision (Benefit)	19	68	(544)	---	335
Net (Loss) Income	(7,044)	(5,901)	(10,506)	(6,011)	1,065
Diluted (Loss) Earnings per Common Share	(0.19)	(0.16)	(0.32)	(0.19)	0.03

Selected Balance Sheet Data:	At June 30,				
	2005	2004	2003	2002	2001
Working Capital	\$8,001	\$3,413	\$4,146	\$8,002	\$6,392
Total Assets	19,680	16,367	18,920	28,100	38,887
Total Liabilities	9,253	3,734	3,484	2,151	6,495
Long-Term Obligations	--	--	--	---	122
Mandatorily Redeemable Preferred Stock	5,324	--	--	---	418
Stockholders' Equity	10,427	12,633	15,436	25,949	31,974

(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>2005</u>	<u>2004</u>	<u>2003</u>
Total Revenues	100.0%	100.0%	100.0%
Gross profit*	73.9	78.8	59.8
Selling, general and administrative expense	92.3	88.8	77.3
Research and development expense	25.2	23.3	21.0
Operating loss	(61.8)	(57.2)	(104.4)
Net loss	(65.8)	(57.7)	(99.0)

\*Based upon percent of net sales

### Results of Operations

#### 1. Year ended June 30, 2005 vs. year ended June 30, 2004

#### Revenues

Net sales of \$9.5 million for fiscal year 2005 declined \$0.5 million when compared to net sales of \$10.0 million for fiscal year 2004. The decline is due to lower sales of the Company's Chromax® chromium picolinate products (\$0.5 million).

Other revenues of \$1.2 million for fiscal year 2005 increased \$1.0 million when compared to \$0.2 million in fiscal year 2004. In fiscal year 2005, the Company received a \$1.0 million non-refundable payment from ImmuCell Corporation for waiving its right to receive potential milestone and royalty payments for a majority of the animal health applications covered by the Company's patented nisin technology.

#### Cost of Goods Sold

Cost of goods sold of \$2.5 million in fiscal year 2005 increased \$0.4 million when compared to cost of goods sold of \$2.1 million in fiscal year 2004. The increase was due to product mix (\$0.2 million), as well as royalty payments made in conjunction with the sale of the Company's Chromax® chromium picolinate product for animal uses (\$0.2 million).

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses of \$9.9 million for fiscal year 2005 increased \$0.8 million when compared to \$9.1 million for fiscal 2004. Expenditures related to the marketing of the Company's first branded products increased \$0.8 million when compared to fiscal year 2004.

## Research and Development

Research and development expenses of \$2.7 million in fiscal year 2005 increased \$0.3 million when compared to \$2.4 million in fiscal year 2004. The increase is due primarily to continued spending to validate 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. Future research and development expenses should be partially offset by an increased number of clinical studies that are being funded by the National Institutes of Health (NIH) to further confirm the role of chromium picolinate in treating various health conditions.

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 was completed in 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.

## Interest Expense

An increase in interest expense of \$0.5 million in fiscal year 2005 is primarily due to accretion of the debt discount and amortization of debt issuance costs related to the 6% Series I Convertible Preferred Stock issued on March 31, 2005.

## Liquidity and Capital Resources

Unrestricted cash, cash equivalents and short-term investments at June 30, 2005 of \$8.7 million increased \$4.5 million when compared to \$4.2 million at June 30, 2004. As of June 30, 2005, the Company had working capital of \$8.0 million compared to working capital of \$3.4 million as of June 30, 2004. On March 31, 2005, the Company entered into a Securities Purchase Agreement under which the Company sold to private investors 9,600 shares of 6% Series I Convertible Preferred Stock and warrants to purchase 2,948,662 shares of Common Stock for gross proceeds of \$9.6 million.

Net cash used in operating activities in fiscal year 2005 was \$2.9 million compared to \$2.5 million in the comparable period a year ago. Partially offsetting the increase in the net loss in fiscal year 2005 of \$7.0 million versus the net loss in fiscal year 2004 of \$5.9 million, were positive changes in net operating assets and liabilities, primarily due to improved cash collections of \$0.8 million.

Net cash used in investing activities in fiscal year 2005 was \$7.8 million compared to net cash used of \$2.4 million in fiscal year 2004. In fiscal year 2005, the Company invested \$6.0 million from the gross proceeds of its 6% Series I Convertible Preferred Stock sale in short-term investments. In addition, the Company used cash of \$1.2 million as security related to a litigation which is pending resolution of an appeal.

Net cash provided by financing activities was \$9.2 million in fiscal year 2005 compared to \$3.0 million in fiscal year 2004. On March 31, 2005, the Company entered into a Securities Purchase Agreement under

which the Company sold to private investors 9,600 shares of 6% Series I Convertible Preferred Stock and warrants to purchase 2,948,662 shares of Common Stock for net proceeds of \$9.2 million.

The Company believes that cash, short-term investments and cash generated from operations will provide sufficient liquidity.

### Operating Loss

Operating loss for fiscal year 2005 was \$6.6 million compared to \$5.9 million for fiscal year 2004. Expenditures related to marketing of its first branded products were the primary reason for the change.

Future increases in marketing and research and development expenses over the present levels may 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.

## 2. 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.

Future increases in marketing and research and development expenses over the present levels 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 on-going basis, the Company evaluates its estimates, including those related to uncollectible accounts receivable, inventories, 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.

### Contractual Obligations

The Company's contractual obligations are comprised of an operating lease for its corporate headquarters, as well as a long-term obligation to Series I convertible preferred stockholders as follows:

(in thousands)	<u>Total</u>	Payments due by period		
		<u>Less than One Year</u>	<u>1 – 3 Years</u>	<u>3 - 5 Years</u>
Operating base obligations	1,349	282	1,067	
Long-term obligations	9,600	---	---	9,600

### Significant New Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123(R), "Share-Based Payment" which establishes standards for transactions in which an entity exchanges its equity instruments for goods or services. This standard focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, including issuance of stock options to employees. SFAS No. 123(R) is effective for the Company beginning with the first quarter of fiscal year 2006. We believe that SFAS No. 123(R) may reduce profitability or increase losses in future periods.

### **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**

Not applicable.

### **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, 2005, 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.

## 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 (52)	1999	President, Chief Executive Officer, and Director
John H. Gutfreund (75)	2000	Chairman of the Board
P. George Benson, PhD (59)	1998	Director
John L. Cassis (57)	2005	Director
Warren D. Cooper, MD (52)	2002	Director
Audrey T. Cross, PhD (60)	1995	Director
Paul Intlekofer (37)	2002	Chief Financial Officer and Senior Vice President, Corporate Development
Marvin Moser, MD (81)	1997	Director

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 Rutgers Business School at Rutgers University and a professor of decision sciences at the Carlson School of Management of the University of Minnesota. In 1996, Business News New Jersey named Dr. Benson one of New Jersey's "Top 100 Business People." In 1997, he was appointed to a three-year term as one of nine judges for the Malcolm Baldrige National Quality Award. In 2004, the U.S. Secretary of Commerce appointed him to the Board of Overseers for the Baldrige National Quality Award and, in 2005, appointed him chairman of the Board of Overseers. Earlier in his career, Dr. Benson worked in personnel planning for the Army Security Agency and in information systems for Bell Telephone Laboratories. Dr. Benson serves on the boards of directors of AGCO, Inc. and Crawford & Company. He received a BS in mathematics from Bucknell University and a PhD in business from the University of Florida.

John L. Cassis was elected a Director of the Company in April 2005. Mr. Cassis is a Managing Partner of Cross Atlantic Partners, a healthcare venture capital firm, a position he has held since joining the firm in 1994. He was formerly a Director of Salomon Brothers Venture Capital, which he joined in 1986 and headed from 1990 to 1994. From 1981 to 1986, he was President of Tower hall, a development banking company he founded. From 1976 to 1981, he was a Managing Director of Ardshiel Associates, Inc., a merchant bank. In 1972, Mr. Cassis joined Johnson & Johnson ("J&J"), where he had direct operating experience, founded the J&J Development Corporation, that firm's venture capital arm, and was J&J's Manager of Acquisitions. He

served on the boards of directors of many companies, including IMPATH, Inc. (Chairman), Dome Imaging Systems, Inc. (Chairman), ILEX Oncology, Inc. and NOMOS Corporation, and currently holds directorships in Medivance, Inc., Galt Associates, Inc., Eximias Pharmaceutical Corp., and Medco Health Solutions. Mr. Cassis received a BA from Harvard University and an MBA from the Harvard Business School.

Warren D. Cooper, MD was elected a Director of the Company in April 2002. Dr. Cooper has been President and CEO of Prism Pharmaceuticals, Inc., a privately held specialty pharmaceutical company that commercializes products for the treatment of cardiovascular disease, since September 2004. From 1999 to 2004, Dr. Cooper was president 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 Emeritus and board member of the Aperture Foundation. Mr. Gutfreund is also a director of AccuWeather, Inc., Compudyne Corporation, Evercel Inc., GVI Security Solutions, 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 was senior medical consultant at the National High Blood Pressure Education Program of the National Heart, Lung and Blood Institute from 1974 to 2002. 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 500 publications. He has authored or contributed to more than 30 books and numerous physician and patient education programs. He has served as chairman or a member of numerous national committees that have established guidelines for the management of hypertension and cardiovascular disease. 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.

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.

#### Director Compensation

During the fiscal year ended June 30, 2005, non-management Directors each received a quarterly director's fee of \$1,800 and the Chairman of the Board received a quarterly director's fee of \$3,600. Each non-management Director also received \$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, 2005, at an exercise price of \$1.02. Effective July 1, 2005, non-management Directors each receive a quarterly director's fee of \$2,500 and the Chairman of the Board receives a quarterly director's fee of \$3,750. Each non-management Director also receives \$750 for each board meeting, \$300 for each committee meeting, and options to purchase 25,000 shares of Common Stock. Upon joining the board, each non-management Director receives options to purchase 20,000 shares of common stock.

#### 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. The Audit Committee held four meetings during the fiscal year ended June 30, 2005.

##### Compensation Committee

The Board of Directors has a Compensation Committee which consists of independent directors Audrey T. Cross, John H. Gutfreund, and John L. Cassis. The Compensation Committee held two meetings during the fiscal year ended June 30, 2005.

##### 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, 2004 through June 30, 2005, 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 2005 and (ii) certain other persons that served as executive officers in fiscal year 2005 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	7/1/02 – 6/30/03	275,000		1,175,000	
	7/1/03 – 6/30/04	296,153 <sup>(4)</sup>			
	7/1/04 – 6/30/05	321,154	25,000		
Paul Intlekofer, Chief Financial Officer and Senior Vice President, Corporate Development	7/1/02 – 6/30/03	190,731		1,050,000	37,500 <sup>(3)</sup>
	7/1/03 – 6/30/04	219,135	10,000		
	7/1/04 – 6/30/05	244,901	50,000		
Benjamin T. Sporn, Vice President, General Counsel and Secretary <sup>(5)</sup>	7/1/02 – 6/30/03	207,500		225,000	
	7/1/03 – 6/30/04	194,808			
	7/1/04 – 6/30/05	96,923	--		75,000 <sup>(6)</sup>

(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.

(5) During fiscal year 2005, Mr. Sporn's status changed from employee to consultant.

(6) Fees earned in a consulting capacity during fiscal year 2005.

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

**Employment and Consulting Agreements**

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	
Name	Number Of Securities Underlying Options/SARs Granted (#)	Percent Of Total Options/SARs Granted To Employees In Fiscal Year	Exercise Of 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 realized (\$)	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	626,666	433,334	\$160,166	\$116,334
Gail Montgomery	0	0	1,181,666	718,334	\$107,333	\$162,917
Benjamin T. Sporn	0	0	454,500	18,000	\$51,750	\$--0--

## Pension Plans

### Nutrition 21, Inc.

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. Eligible employees of the Company were, until September 19, 2004, entitled to participate and to accrue benefits in the AB Mauri Food Inc. Retirement Plan, a non-contributory pension plan (the "Pension Plan") maintained by AB Mauri Food Inc. Service with the Company after September 19, 2004 will be considered solely for purposes of vesting and for determining eligibility for early retirement benefits. Ms. Montgomery and Mr. Sporn are fully vested in the Pension Plan. Mr. Intlekofer will vest in the Pension Plan in September 2007 if he is then employed by the Company. Ms. Montgomery will receive approximately \$14,000 in annual benefits under the Pension Plan at age 65. If Mr. Intlekofer vests in the Pension Plan, he will receive approximately \$5,900 in annual benefits under the Plan at age 65. Commencing January 1, 2005, Mr. Sporn is receiving \$26,731 annual pension under the Pension Plan, that will continue after his death for the life of his wife.

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

The following table sets forth, as of September 17, 2005, 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)

Name and Address	No. of Shares	% of Class
P. George Benson (2)	115,000	*
John L. Cassis (3)	1,999,037	4.99
Warren D. Cooper (4)	55,000	*
Audrey T. Cross (5)	139,000	*
John H. Gutfreund (6)	235,000	*
Paul Intlekofer (7)	1,073,716	2.74
Gail Montgomery (8)	1,760,812	4.43
Marvin Moser (9)	210,000	*
Wyeth (10) 5 Giralda Farms Madison, NJ 07940	3,478,261	9.12
<input type="checkbox"/> All Executive Officers and Directors as a Group (8 persons) (11)	5,587,565	13.51

\* 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 105,000 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(3) Consists of 1,989,037 shares of Common Stock issuable on conversion of 2,493 shares of Preferred Stock owned by affiliates of Mr. Cassis and 10,000 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans. Does not include 404,262 additional shares of Common Stock that are issuable to these affiliates on conversion of 507 additional shares of Preferred Stock subject to a restriction (the “4.99% Restriction”) that limits the right of a holder to convert Preferred Stock and to exercise Warrants if beneficial ownership of the holder and its affiliates would exceed 4.99% of the shares of Common Stock that would then be outstanding after giving effect to such conversion or exercise. Also does not include 921,456 additional shares of Common Stock that these affiliates may acquire upon exercise of Warrants that are exercisable commencing October 1, 2005 subject to the 4.99% Restriction. Mr. Cassis disclaims beneficial ownership of the securities referred to in this footnote except to the extent of his pecuniary interest in these securities.

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

(5) Includes 135,000 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(6) Includes 85,000 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(7) Includes 1,026,666 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

(8) Includes 1,575,000 shares issuable upon exercise of currently exercisable options under the Company's Stock Option Plans.

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

(10) Formerly American Home Products Corporation.

(11) Includes 3,166,666 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, 2005.

### 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	3,290,461	\$1.17	5,019,500 (4)
Equity compensation plans not approved by security holders	(1) 2,397,167 (2) 0 (3) 541,950	\$0.44  \$0.95	92,833 2,500,000
Total	6,229,578		7,612,333

(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 (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.

(4) Includes 5,000,000 options available from the 2005 Stock Option Plan, whose purpose is to provide additional incentives to officers, directors, employees and others who render services to the Company to advance the interests of the Company (Exhibit 10.77).

### 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. During fiscal year 2005, BP sold, in a private placement, all of its remaining shares of Common Stock.

**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, 2005 and 2004.

Set forth below is certain information concerning audit and related services rendered to the Company by J.H. Cohn LLP for the fiscal years ended June 30, 2005 and 2004. As indicated below, in addition to reviewing financial statements, J.H. Cohn LLP provided other services in the fiscal years ended June 30, 2005 and 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 years ended June 30, 2005 and June 30, 2004, J. H. Cohn LLP billed the Company \$102,000 and \$95,000, respectively, for audit services.

*Audit related fees.* In the fiscal years ended June 30, 2005 and June 30, 2004, J.H. Cohn LLP billed the Company \$21,000 and \$9,000, respectively, for services related to registrations on Forms S-3 and S-8. In the fiscal year ended June 30, 2005, Ernst & Young LLP billed the Company \$22,500 for services related to registrations on Forms S-3 and S-8.

*Tax Fees.* In the fiscal years ended June 30, 2005 and June 30, 2004, J. H. Cohn LLP billed the Company \$24,000 and \$20,000, respectively, for tax compliance services.

*All other fees.* None



**Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

(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.

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 27, 2005

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below, as of September 27, 2005, 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/ John L. Cassis  
John L. Cassis, Director

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

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

/s/ Marvin Moser  
Marvin Moser, 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)
- 10.77 Nutrition 21, Inc. 2005 Stock Plan (23)
- 23.1 Consent of J.H. Cohn 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)

- 
- (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, 2005

	<u>PAGE</u>
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	F-2
CONSOLIDATED BALANCE SHEETS AT JUNE 30, 2005 AND 2004	F-3
CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE YEARS ENDED JUNE 30, 2005, 2004 AND 2003	F-5
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE YEARS ENDED JUNE 30, 2005, 2004 AND 2003	F-6
CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED JUNE 30, 2005, 2004 AND 2003	F-7
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS	F-8

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, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the three year period ended June 30, 2005. Our audits also included the 2005, 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 audits.

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, 2005 and 2004, and their consolidated results of operations and cash flows for each of the years in the three year period ended June 30 2005, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the consolidated financial statement schedule referred to above, 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 22, 2005



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

	June 30, <u>2005</u>	June 30, <u>2004</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 675	\$2,164
Short-term investments	8,000	2,000
Restricted cash	1,225	--
Accounts receivable (less allowance for doubtful accounts and returns of \$9 in 2005 and \$10 in 2004)	779	1,342
Other receivables	279	257
Inventories	582	1,163
Prepaid expenses and other current assets	<u>390</u>	<u>221</u>
Total current assets	11,930	7,147
Property and equipment, net	249	314
Patents, trademarks and other intangibles (net of accumulated amortization of \$17,446 in 2005 and \$15,444 in 2004)	7,013	8,719
Other assets	<u>488</u>	<u>187</u>
<b>TOTAL ASSETS</b>	<b><u>\$19,680</u></b>	<b><u>\$16,367</u></b>

See accompanying notes to consolidated financial statements.

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

	<u>JUNE 30,</u> <u>2005</u>	<u>JUNE 30,</u> <u>2004</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>LIABILITIES:</b>		
Current liabilities, accounts payable and accrued expenses	\$3,929	\$3,734
6% Series I convertible preferred stock subject to mandatory redemption (redemption value \$9,600)	<u>5,324</u>	<u>---</u>
<b>TOTAL LIABILITIES</b>	<u><b>9,253</b></u>	<u><b>3,734</b></u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, \$0.01 par value, authorized 5,000,000 shares, 9,600 shares designated as Series I, issued and outstanding	--	--
Common stock, \$0.005 par value, authorized 65,000,000 shares; 38,156,695 issued and outstanding at June 30, 2005 and 37,991,988 issued and outstanding at June 30, 2004	190	190
Additional paid-in capital	72,205	67,367
Accumulated deficit	<u>(61,968)</u>	<u>(54,924)</u>
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<u><b>10,427</b></u>	<u><b>12,633</b></u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u><b>\$19,680</b></u>	<u><b>\$16,367</b></u>

See accompanying notes to consolidated financial statements.

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

	<u>YEAR ENDED JUNE 30,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net sales	\$9,462	\$9,990	\$10,265
Other revenues	<u>1,249</u>	<u>242</u>	<u>350</u>
TOTAL REVENUES	10,711	10,232	10,615
Cost of goods sold	<u>2,469</u>	<u>2,119</u>	<u>4,129</u>
GROSS PROFIT	8,242	8,113	6,486
Selling, general & administrative expenses	9,885	9,088	8,201
Research & development expenses	2,696	2,382	2,232
Depreciation & amortization expenses	2,280	2,497	2,691
Charge for impairment of intangibles	<u>----</u>	<u>-----</u>	<u>4,443</u>
OPERATING LOSS	(6,619)	(5,854)	(11,081)
Interest income	91	46	64
Interest expense	<u>(497)</u>	<u>(25)</u>	<u>(33)</u>
LOSS BEFORE INCOME TAXES (BENEFIT)	(7,025)	(5,833)	(11,050)
Income taxes (benefit)	<u>19</u>	<u>68</u>	<u>(544)</u>
NET LOSS	<u>\$(7,044)</u>	<u>\$(5,901)</u>	<u>\$(10,506)</u>
Basic and diluted loss per common share	<u>\$(0.19)</u>	<u>\$(0.16)</u>	<u>\$(0.32)</u>
Weighted average number of common shares – basic and diluted	<u>38,041,426</u>	<u>36,767,826</u>	<u>33,309,371</u>

See accompanying notes to consolidated financial statements.

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, 2002	471	33,048,655	63,936	(38,501)	(122)	25,949
Preferred stock dividends declared	--	--	--	--	--	(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 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
Exercise of stock options and warrants	--	103,732	50	--	--	50
Issuance of common stock for compensation	--	60,975	25	--	--	25
Issuance of warrants and beneficial conversion features related to 6% Series I convertible preferred stock	--	--	4,698	--	--	4,698
Charge for stock appreciation rights	--	--	23	--	--	23
Issuance of warrants for services	--	--	42	--	--	42
Net loss for the period	--	--	--	(7,044)	--	(7,044)
Balance at June 30, 2005	\$--	38,156,695	\$72,205	\$(61,968)	\$--	\$10,427

See accompanying notes to consolidated financial statement

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

	<u>YEAR ENDED JUNE 30,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Cash flows from operating activities:			
Net loss	\$(7,044)	\$(5,901)	\$(10,506)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and equipment	181	177	205
Amortization of intangibles	2,099	2,320	2,486
Impairment write-off	--	--	4,443
Accretion of preferred stock and amortization of deferred financing costs	376	--	--
Loss on disposal of equipment	--	--	7
Issuance of warrants for services	42	52	47
Charge for stock appreciation rights	23	35	--
Changes in operating assets and liabilities:			
Accounts receivable	563	(202)	1,079
Other receivables	(23)	843	(3)
Inventories	582	(28)	(60)
Prepaid expenses and other current assets	(169)	(25)	591
Other assets	186	12	21
Accounts payable and accrued expenses	<u>236</u>	<u>231</u>	<u>1,354</u>
Net cash used in operating activities	<u>(2,948)</u>	<u>(2,486)</u>	<u>(336)</u>
Cash flows from investing activities:			
Contingent payments for acquisitions	(176)	(143)	(135)
Purchases of property and equipment	(116)	(12)	(86)
Payments for patents and trademarks	(233)	(263)	(350)
Proceeds from sale of equipment	--	--	50
Redemption of investments available for sale	--	3,500	1,000
Purchase of investments available for sale	(6,000)	(5,500)	--
Increase in restricted cash	<u>(1,225)</u>	<u>--</u>	<u>--</u>
Net cash (used in)/ provided by investing activities	<u>(7,750)</u>	<u>(2,418)</u>	<u>479</u>
Cash flows from financing activities:			
Purchase of common stock for treasury	--	--	(38)
Proceeds from stock option and warrants exercised	50	6	--
Preferred stock dividends paid	--	(2)	(20)
Net proceeds from private placement of common stock	--	3,005	--
Proceeds from private placement of mandatorily redeemable Series I convertible preferred stock, net of issuance costs	<u>9,159</u>	<u>-----</u>	<u>-----</u>
Net cash provided by (used in) financing activities	<u>9,209</u>	<u>3,009</u>	<u>(58)</u>
Net (decrease) increase in cash and cash equivalents	(1,489)	(1,895)	85
Cash and cash equivalents at beginning of year	<u>2,164</u>	<u>4,059</u>	<u>3,974</u>
Cash and cash equivalents at end of year	<u>\$ 675</u>	<u>\$ 2,164</u>	<u>\$ 4,059</u>

See accompanying notes to consolidated financial statements.

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 interest-earning liquid investments with a maturity of three months or less when acquired to be cash equivalents. Investments in marketable securities with maturities beyond one year are classified as current assets because of their highly liquid nature. 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.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

f) Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization is provided using the straight-line method over the related assets' estimated useful lives or the term of the lease, if shorter. 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.

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. Revenue is recognized only where collectibility of accounts receivable is reasonably assured. 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. In fiscal year 2005, the Company received a non-recurring \$1.0 million payment from ImmuCell Corporation for waiving its right to receive potential milestone and royalty payments for a majority of the animal health applications covered by the Company's patented nisin technology.

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.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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 is recognized initially in the consolidated financial statements for 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):

	<u>2005</u>	Year-ended June 30, <u>2004</u>	<u>2003</u>
Net loss as reported	\$(7,044)	\$(5,901)	\$(10,506)
Deduct: total stock-based employee compensation expense determined under fair value based method for all awards	<u>(263)</u>	<u>(25)</u>	<u>(256)</u>
Pro forma net loss	<u>\$(7,307)</u>	<u>\$(5,926)</u>	<u>\$(10,762)</u>
Loss per common share			
Basic – as reported	\$(0.19)	\$(0.16)	\$(0.32)
Basic – pro forma	\$(0.19)	\$(0.16)	\$(0.32)
Diluted – as reported	\$(0.19)	\$(0.16)	\$(0.32)
Diluted – pro forma	\$(0.19)	\$(0.16)	\$(0.32)



NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

As a result of amendments to SFAS No. 123, the Company will be required to expense the fair value of employee stock options over the vesting period beginning with its fiscal quarter ending September 30, 2005.

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) Advertising costs

Advertising costs are expensed as incurred. The amount charged to expense during fiscal years 2005, 2004 and 2003 was \$1.4 million, \$0.9 million and \$0.6 million, respectively.

n) Reclassifications

Certain reclassifications have been made to prior years' financial statement amounts to conform to the 2005 presentation.

Note 2: SHORT-TERM INVESTMENTS

Short-term investments are comprised as follows (in thousands):	June 30,	
	<u>2005</u>	<u>2004</u>
Available for sale:		
1.8% corporate bond, maturing 6/1/05	\$ --	\$1,000
2.03% corporate bond, maturing 12/22/05	1,000	1,000
3.87% corporate bond, maturing 12/15/06	1,000	--
Variable corporate bonds, maturing 5/5/06	1,000	--
Auction rate securities <sup>(1)</sup>	<u>5,000</u>	<u>--</u>
<b>TOTAL</b>	<b><u>\$8,000</u></b>	<b><u>\$2,000</u></b>

<sup>(1)</sup> Auction rate securities are instruments whose interest rate or dividends are reset at specific frequencies. The typical reset periods are either 28 or 35 days, but may be as short as seven days or as long as one year.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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. 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, 2005. The Company places its cash primarily in market interest rate accounts, overnight investments and short-term investments. The Company had \$0.7 million invested in mutual money market funds and \$8.0 million invested in short-term investments at June 30, 2005.

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 years 2005 and 2004, two customers accounted for approximately 34% and 35% of total revenues, respectively. For fiscal year 2003, one customer accounted for approximately 18% of total revenues. In addition, three customers accounted for 40% of accounts receivable, net at June 30, 2005, while three customers accounted for 57% of accounts receivable, net at June 30, 2004.

Note 4: PROPERTY AND EQUIPMENT, NET

The components of property and equipment, net, at June 30, 2005 and 2004 are as follows (in thousands):

	<u>2005</u>	<u>2004</u>
Furniture and fixtures	\$492	\$422
Machinery and equipment	135	135
Office equipment & leasehold improvements	542	542
Computer equipment	<u>824</u>	<u>778</u>
	1,993	1,877
Less: accumulated depreciation and amortization	<u>(1,744)</u>	<u>(1,563)</u>
Property and equipment, net	<u>\$249</u>	<u>\$314</u>

Note 5: PATENTS AND TRADEMARKS, NET

During fiscal years 2005, 2004 and 2003, changes in intangible assets relate to the investment of \$0.4 million, \$0.2 million and \$0.5 million, respectively, in existing patents, which will be amortized over the remaining life of the patents. No significant residual value is estimated for these intangible assets. Intangible asset amortization expense was \$2.1 million for fiscal year 2005, \$2.3 million for fiscal year 2004 and \$2.5 million for fiscal year 2003. The components of intangible assets are as follows (in thousands):

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 5: PATENTS AND TRADEMARKS, NET (continued)

	June 30,			
	2005		2004	
	Gross Carrying <u>Amount</u>	Accumulated <u>Amortization</u>	Gross Carrying <u>Amount</u>	Accumulated <u>Amortization</u>
Patents and licenses	\$8,623	\$(7,753)	\$8,468	\$(7,246)
Trademarks, trade names and other	<u>15,836</u>	<u>(9,693)</u>	<u>15,695</u>	<u>(8,198)</u>
Intangible assets	<u>\$24,459</u>	<u>\$(17,446)</u>	<u>\$24,163</u>	<u>\$(15,444)</u>

Amortization expense for the net carrying amount of intangible assets at June 30, 2005 is estimated to be approximately \$2.1 million in fiscal year 2006 and \$1.9 million in fiscal years 2007 through 2009, respectively.

Note 6: ACCOUNTS PAYABLE AND ACCRUED EXPENSES

The following items are included in accounts payable and accrued expenses at June 30, 2005 and 2004 (in thousands):

	2005	2004
Accounts payable	\$1,557	\$1,130
Consulting and professional fees payable	100	172
Accrued compensation and related expense	369	302
Accrued termination expense	1,225	1,069
Other accrued expenses	<u>678</u>	<u>1,061</u>
	<u>\$3,929</u>	<u>\$3,734</u>

Note 7: SERIES I CONVERTIBLE PREFERRED STOCK SUBJECT TO MANDATORY REDEMPTION

On March 31, 2005, the Company entered into a Securities Purchase Agreement (the "Agreement") under which the Company sold to private investors 9,600 shares of 6% Series I Convertible Preferred Stock and warrants to purchase 2,948,662 shares of Common Stock for gross proceeds of \$9.6 million. Each share of Preferred Stock has a stated value of \$1,000 per share. The Preferred Stock is convertible into common stock at the option of the holders at \$1.2535 per share, subject to anti-dilution provisions. Subject to certain conditions, the Company can force conversion of the Preferred Stock if the volume weighted average price of the common stock is at least \$3.76 for 20 consecutive trading days. The Preferred Stock pays cumulative dividends at the annual rate of 6%. Dividends are payable in cash, provided that in certain circumstances dividends may be paid in shares of common stock valued at 90% of the then volume weighted average price. The Company must redeem the Preferred Stock at the original issue price plus accrued dividends on March 31, 2009. The Agreement also provides for early redemption of the Preferred Stock on the occurrence of certain default events. The Warrants are exercisable commencing October 1, 2005 and ending on March 31, 2010 at \$1.3104 per share subject to anti-dilution provisions and other limitations. The Warrants may be exercised on a cashless basis (i.e., by deducting from the number of shares otherwise issuable on exercise a number of shares that has a then market value equal to the exercise price) after March 31, 2006 so long as no registration statement is in effect with respect to the sale of shares issuable upon exercise.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 7: SERIES I CONVERTIBLE PREFERRED STOCK SUBJECT TO MANDATORY REDEMPTION (continued)

In connection with the Agreement, the Company recorded a long-term liability of \$5.0 million with a resultant increase to additional paid-in capital of \$4.6 million, relating to a beneficial conversion feature of the preferred stock and the fair value of the warrants. Dividends are classified as interest expense. Related issuance costs of \$0.5 million, classified as other assets on the consolidated balance sheet, are amortized to interest expense over the term of the preferred stock. In addition, debt discount is being accreted and charged to interest expense over the term of the preferred stock. In fiscal year 2005, \$0.3 million was charged to interest expense for accretion.

Note 8: STOCKHOLDERS' EQUITY

2005 Stock Plan

The Company's shareholders approved a 2005 Stock Plan (the "Plan"). The Plan provides for the grant of options to purchase shares of the Company's common stock to provide additional incentives to officers, directors, employees and others who render services to the Company. The aggregate number of shares of common stock, which may become subject to options shall not exceed 5,000,000. Approximately 5,000,000 options remain available for grant under the Plan at June 30, 2005.

Warrants

In addition to the warrants issued to the private investors, as noted in Note 7 above, the Company, from time to time, has issued 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:

	<u>Number of warrants</u>	<u>Exercise price per share</u>
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	601,950	\$0.40-\$3.26
Issued	312,461	\$0.62-\$1.28
Exercised	(20,000)	\$0.46-\$0.63
Cancelled	<u>(60,000)</u>	\$0.89-\$1.38
Outstanding at June 30, 2005	<u>834,411</u>	\$0.40-\$3.26

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

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8: STOCKHOLDERS' EQUITY (continued)

Warrants outstanding and exercisable at June 30, 2005 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 - \$0.81	350,000	1.81	\$0.66	350,000	\$0.66
\$1.05 - \$3.26	484,411	4.51	\$1.34	191,950	\$1.46
	<u>834,411</u>			<u>541,950</u>	

The Company recorded compensation expense associated with the issuance of warrants to non-employees for services rendered of \$42 thousand, \$52 thousand and \$47 thousand during fiscal years 2005, 2004 and 2003, respectively.

Options

In addition to the 2005 Stock Plan, the Company had adopted six other Stock Option Plans ("Plans") whereby options to purchase an aggregate of 11,250,000 shares of the Company's common stock were originally authorized for grant to employees, consultants and others who rendered 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 2006 and 2011. Approximately 28,600 options remain available for grant under these Plans at June 30, 2005.

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

	Number of options	Exercise price per share
Outstanding at June 30, 2002	3,639,989	\$0.55 - \$5.63
Issued	3,466,000	\$0.31 - \$0.71
Exercised	--	--
Cancelled	(591,987)	\$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	(1,881,616)	\$0.38 - \$5.19
Outstanding at June 30, 2004	5,254,786	\$0.31 - \$5.63
Issued	677,000	\$0.47 - \$1.16
Exercised	(83,733)	\$0.38 - \$1.25
Cancelled	(160,425)	\$0.37 - \$3.09
Outstanding at June 30, 2005	<u>5,687,628</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.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8: STOCKHOLDERS' EQUITY (continued)

Options outstanding and exercisable at June 30, 2005 are as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.31 - \$0.94	3,974,667	7.40	\$0.53	2,253,311	\$0.52
\$0.95 - \$1.44	1,193,361	6.42	\$1.17	1,092,668	\$1.18
\$1.50 - \$2.94	364,600	3.52	\$2.19	343,000	\$2.21
\$3.06 - \$5.63	<u>155,000</u>	1.98	\$3.80	<u>155,000</u>	\$3.80
	<u>5,687,628</u>			<u>3,843,979</u>	

The per share weighted-average fair value of stock options granted during fiscal years 2005, 2004 and 2003 was \$0.49, \$0.25 and \$0.06, respectively, on the date of grant using the Black Scholes option-pricing model with the following weighted-average assumptions:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Risk-free interest rate	3.0%	2.3%	2.2%
Expected life-years	2.4	2.5	2.5
Expected volatility	104.1%	125.5%	45.4%
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 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 Series H 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 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 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.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 10: LOSS PER COMMON SHARE

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

	<u>Year ended June 30,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Basic and diluted loss per common share:			
Net loss	\$(7,044)	\$(5,901)	\$(10,506)
Less: Dividends on preferred shares	<u>--</u>	<u>--</u>	<u>(16)</u>
Loss applicable to common stockholders	<u>\$(7,044)</u>	<u>\$(5,901)</u>	<u>\$(10,522)</u>
Weighted average shares	<u>38,041,426</u>	<u>36,767,826</u>	<u>33,309,371</u>
Basic and diluted loss per common share	<u>\$(0.19)</u>	<u>\$(0.16)</u>	<u>\$(0.32)</u>

Diluted loss per share for the fiscal years ended June 30, 2005, 2004 and 2003, does not reflect the incremental shares from the assumed conversion of preferred stock, options and warrants (1,737,071, 505,693 and 396,586 shares, respectively) as the effect of such inclusion would be anti-dilutive.

Note 11: BENEFIT PLANS

Through September 19, 2004, eligible employees of the Company were entitled to participate and to accrue benefits in the AB Mauri Food Inc. Retirement Plan, a non-contributory pension plan (the "Pension Plan") maintained by AB Mauri Food Inc. No additional pension benefits accrue under the Pension Plan 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.

During fiscal years 2005, 2004, and 2003, the Company made contributions to the Retirement Plan of \$0.2 million, \$0.2 million and \$0.1 million, respectively. The Company is obligated to make a payment of \$0.2 million each year for the next three years.

In addition, the Company also maintains a 401(K) deferred contribution plan. Contributions to the plan for the fiscal years 2005, 2004 and 2003 were \$0.1 million each year.

Note 12: INCOME TAXES

The provisions for income taxes for the fiscal years ended June 30, 2005, 2004 and 2003 consist of the following (in thousands):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Current	\$19	\$68	\$(1,182)
Deferred	<u>--</u>	<u>--</u>	<u>638</u>
	<u>\$19</u>	<u>\$68</u>	<u>\$(544)</u>

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 12: INCOME TAXES (continued)

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

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Income tax (benefit) at U.S. statutory rate	\$(3,379)	\$(1,983)	\$(3,757)
Increase/ (reduction) in income taxes resulting from:			
Change in valuation allowance	3,366	1,983	4,184
State taxes, net of federal	19	68	(663)
Other items	<u>13</u>	<u>--</u>	<u>(308)</u>
Total income tax (benefit)	<u>\$19</u>	<u>\$ 68</u>	<u>\$(544)</u>

The tax effects of temporary differences that give rise to deferred taxes and deferred tax assets and deferred tax liabilities at June 30, 2005 and 2004 are presented below (in thousands):

	<u>2005</u>	<u>2004</u>
Deferred tax assets:		
Net operating loss carryforwards	\$6,919	\$4,392
Accrued expenses	741	833
Inventory reserve	24	2
Intangible and fixed assets	5,794	4,886
Other	<u>4</u>	<u>3</u>
Total gross deferred tax assets	13,482	10,116
Less valuation allowance	<u>(13,482)</u>	<u>(10,116)</u>
Net deferred tax assets	<u>\$ ---</u>	<u>\$ ---</u>

At June 30, 2005, the Company has available, for federal and state income tax purposes, net operating loss carry forwards of approximately \$17.7 million and \$10.7 million, respectively, expiring through 2025. 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 13: COMMITMENTS AND CONTINGENCIES

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 \$0.6 million. The Company and QVC have agreed to settle this suit for a payment by the Company of \$0.4 million. This amount has been included in accounts payable and accrued expenses at June 30, 2005.



NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 13: COMMITMENTS AND CONTINGENCIES (continued)

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 Company, in the same lawsuit, filed on March 4, 2005, a Third-Party Complaint for indemnity against Marvin Segel, its on-air spokesperson for Lite-Bites products. 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. On November 1, 2004 the United States District Court for the Southern District of New York denied a motion by the Company to vacate the part of the award that relates to the stock options, i.e. \$709,000 plus interest. The Company appealed the Decision of the District court. On December 13, 2004, the Company posted \$1,225,000 as security with the Clerk of the District Court, pending final resolution of the matter.

The Company in July 2002 granted to Gail Montgomery, President and CEO, options to purchase an aggregate of 850,000 shares of common stock at \$0.39 per share, and 325,000 stock appreciation rights which will vest pro ratably over three years, 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 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.

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 13: COMMITMENTS AND CONTINGENCIES (continued)

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 2009. Rent expense under this operating lease was approximately \$0.4 million in fiscal year 2005, \$0.4 million in fiscal year 2004, and \$0.4 million in fiscal year 2003. Future non-cancelable minimum payments under this lease are as follows (in thousands):

<u>Fiscal Year</u>	<u>Amount</u>
2006	\$ 282
2007	388
2008	388
2009	<u>291</u>
Total	<u>\$1,349</u>

In connection with the Company's purchase agreement for Nutrition 21 on August 11, 1997, the Company made cash payments of \$0.1 million for each of the fiscal years 2005, 2004 and 2003.

Note 14: SUPPLEMENTAL CASH FLOW INFORMATION

	<u>Year ended June 30,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Supplemental disclosure of cash flow information (in thousands)			
Cash paid for interest	\$ --	\$ --	\$ 33
Cash paid for income taxes	19	2	41
Supplemental schedule of non-cash financing activities:			
Obligation for Nutrition 21 contingent payment	31	21	26
Issuance of common stock for conversion of Series G preferred	--	188	283
Issuance of common stock for deferred compensation	25	--	--
Issuance of warrants to purchase 292,461 shares of common stock for services related to 6% Series I convertible preferred stock	248	--	--

Note 15: SPECIAL MEETING OF SHAREHOLDERS

A Special Meeting of Shareholders of Nutrition 21, Inc. (the "Company") was held on June 28, 2005 and adjourned and continued on July 28, 2005.

The following items were approved:

- 1) An increase in authorized shares of common stock from 65,000,000 shares to 100,000,000 shares;
- 2) Removal of price limits that were imposed on issuance and anti-dilution provisions in connection with the Company's recent issuance of preferred stock;

NUTRITION 21, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 15: SPECIAL MEETING OF SHAREHOLDERS (continued)

- 2) Use of common stock for payment of dividends on the preferred stock; and
- 3) Adoption of the Company's 2005 Stock Plan.

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</u>
<u>Fiscal Year 2005</u>				
Revenues	\$2,741	\$3,653	\$2,394	\$1,923
Gross profit	2,131	2,981	1,736	1,394
Loss before income taxes	(1,223)	(282)	(1,858)	(3,662)
Net loss	(1,227)	(287)	(1,868)	(3,662)
Net loss per common share:				
Basic and diluted	\$(0.03)	\$(0.01)	\$(0.05)	\$(0.10)
<u>In thousands, except per share data</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</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 and diluted	\$(0.03)	\$(0.03)	\$(0.03)	\$(0.07)

NUTRITION 21, INC.  
VALUATION AND QUALIFYING ACCOUNTS

<u>Accounts</u>	Balance Beginning of <u>Year</u>	Additions		<u>Deductions</u>	Balance End of <u>Year</u>
		Charged to Cost and <u>Expense</u>	Charged to Other <u>Accounts</u>		
(\$ in thousands)					
Year ended June 30, 2005					
Allowance for doubtful accounts	10	--	--	(1)	9
Deferred tax valuation allowance	10,116	3,366	--	--	13,482
Allowance for returns and allowances	516	(126)	--	--	390*
Allowance for inventory obsolescence	6	54	--	--	60
Year ended June 30, 2004					
Allowance for doubtful accounts	430	(411)	--	(9)	10
Deferred tax valuation allowance	5,791	1,983		--	10,116
Allowance for returns and allowances	1,060	--	2,342**	(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

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

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

## CORPORATE INFORMATION

### Directors

**John H. Gutfreund**

Chairman of the Board

Nutrition 21, Inc.

Senior Advisor

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

**John L. Cassis**

Managing Partner

Cross Atlantic Partners

**Warren D. Cooper, MD**

President and Chief Executive Officer

Prism Pharmaceuticals, 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

### Officers

**Gail Montgomery**

President and Chief Executive Officer

**Paul Intlekofer**

Chief Financial Officer and Senior Vice President,  
Corporate Development

**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