

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 10-KSB/A**

- Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2004.
- or
- 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 0-8092

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**OXIS International, Inc.**

A Delaware corporation  
I.R.S. Employer Identification No. 94-1620407  
6040 N. Cutter Circle, Suite 317  
Portland, OR 97217  
Telephone: (503) 283-3911

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

Securities registered pursuant to Section 12(g) of the Act:  
Common Stock, \$.001 par value

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

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

The Registrant's revenues for its fiscal year ended December 31, 2004 were \$2,364,000.

Aggregate market value of the common equity held by non-affiliates of the Registrant as of December 31, 2004 was \$22,178,453.40.

Number of shares outstanding of Registrant's common stock as of February 25, 2005: 41,308,364 shares.

Certain of the information required by Part III of this Form 10-KSB is incorporated by reference to portions of the Company's definitive form of Proxy Statement which will be filed with the Commission during April 2005 with respect to the Company's Annual Meeting of Shareholders scheduled for June 2005.

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**PART 1**

*This Report on Form 10-KSB/A and the documents incorporated by reference include “forward-looking statements”. To the extent that the information presented in this Report on Form 10-KSB/A discusses financial projections, information or expectations about our business plans, results of operations, products or markets, or otherwise makes statements about future events, such statements are forward-looking. Such forward-looking statements can be identified by the use of words such as “intends”, “anticipates”, “believes”, “estimates”, “projects”, “forecasts”, “expects”, “plans” and “proposes”. Although we believe that the expectations reflected in these forward-looking statements are based on reasonable assumptions, there are a number of risks and uncertainties that could cause actual results to differ materially from such forward-looking statements. These include, among others, the cautionary statements in the “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this Report on Form 10-KSB/A. These cautionary statements identify important factors that could cause actual results to differ materially from those described in the forward-looking statements. When considering forward-looking statements in this Report on Form 10-KSB/A, you should keep in mind the cautionary statements in the “Risk Factors” section above and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section below, and other sections of this Report on Form 10-KSB/A.*

*The statements contained in this Report on Form 10-KSB/A that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements regarding our expectations, objectives, anticipations, plans, hopes, beliefs, intentions or strategies regarding the future. Forward-looking statements include, without limitation, statements regarding: (i) our intention to provide a more effective diagnostic predictor test for patients at risk of cardiac events, and to submit this product for FDA diagnostic approval and subsequently for commercial launch by the first quarter of 2006; (ii) our plans to conduct collaborative research to design an oxidative stress paradigm to diagnose the early onset of potentially fatal human and animal diseases; (iii) the initial focus of such collaborative research including diseases, including Bovine Spongiform Encephalopathy (BSE; Mad Cow Disease); Creutzfeldt Jacob Disease (CJD; human variant of BSE); Type II Diabetes with associated cardiovascular mortality; atherosclerosis and cardiac morbidity; hepatitis with liver failure; and neurodegenerative disorders, such as Alzheimer’s disease and stroke; (iv) our intention to attempt to develop diagnostic biomarkers that can identify at an early stage the presence of a disease state, distinguish which patients are most suited for a particular drug, and provide feedback to the physician on how well the drug is working; (v) our intention to focus on and intensify our efforts to consummate diagnostic, pharmaceutical and nutraceutical relationships and/or strategic partnerships with larger companies for the purpose of further developing and exploiting our antioxidant molecules; (vi) our plan to continue to evaluate our therapeutics classes of small molecular weight antioxidant molecules for further development as our financial resources permit; (vii) our plans to include a new focus on the areas of clinical cardiac predictor testing, biomarker research and the nutraceutical marketplace; (viii) our pursuit of the development of a cardiovascular predictor product intended to provide a more effective diagnostic predictor test for patients at risk of cardiac events before they occur; (ix) our development of such a product through the combination of our MPO assay with other assays currently in-house (as well as with other assays under development); (x) our belief that our Ergothioneine compound may be well suited for development as a nutraceutical supplement that can be sold over the counter and our intent to pursue the development of Ergothioneine for use in such markets; (xi) our expectation that revenues from sales to EMD Biosciences, Inc. for fiscal year 2005 will be similar to those in 2004; (xii) our intention to file new patent applications related to our current products under development, pursue acquisitions on a selective basis, and expand our marketing efforts in both commercial and research markets; (xiii) our estimate that there are more than 10,000 scientists and clinicians who are working directly in research on free radical biochemistry, and who are potential customers for these research assays; (xiv) our belief that our assays offer advantages over conventional laboratory methods, including ease of use, speed, specificity and accuracy; (xv) our*

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*belief that our new products and technologies show considerable promise; (xvi) our belief that we could readily find alternative suppliers, or that we could readily market alternative products with adequate raw material supply; (xvii) our intent to establish and implement a plan to recruit distributors of our products; (xviii) our indication that our future success may depend in part upon the results of clinical trials designed to assess the safety and efficacy of our potential products; (xix) our belief that we have sufficient capital resources to sustain our operations for at least eighteen months and to continue operating in accordance with our current plans for 2005; (xx) our belief that we currently are in compliance with all such regulations and our intention that in the future all of our diagnostic and therapeutic developments will be in compliance with these regulations; (xxi) our belief that our relationship with our employees is good; (xxii) our belief that our facilities are adequate for the immediate future; (xxiii) our belief that the \$6,500,000 in additional capital received in the form of private placement of equity will allow us to continue operating in accordance with our current plans for 2005; (xxiv) our expectation that our research and development expenses will increase as we attempt to develop potential products and the cardiac predictor program; and (xxv) our expectation to have smaller losses in 2005.*

*All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. It is important to note that our actual results could differ materially from those included in such forward-looking statements. Factors that could cause actual results to differ materially from the forward looking statements include, but are not limited to, the following: (1) we may not be able to obtain necessary financing; (2) the cost of complying with the regulatory requirements related to being listed on a stock exchange in France may exceed expectations; (3) Axonyx Inc. holds the voting power to control matters affecting us, and such concentration of voting power could have the effect of delaying, deterring or preventing a change of control; (4) uncertainties exist relating to issuance, validity and ability to enforce and protect patents, other intellectual property and certain proprietary information; (5) the potential for patent-related litigation expenses and other costs resulting from claims asserted against us or our customers by third parties; (6) our products may not meet product performance specifications; (7) new products may be unable to compete successfully in either existing or new markets; (8) availability and future costs of materials and other operating expenses; (9) weakness in the global economy and changing market conditions, together with general economic conditions affecting our target industries, could cause the our operating results to fluctuate; (10) the risks involved in international operations and sales; and (11) disclosure controls cannot prevent all error and all fraud. For a more detailed explanation of such risks, please see the section entitled "Risk Factors" beginning on page 18 of this Report on Form 10-KSB/A. Such risks, as well as such other risks and uncertainties as are detailed in our SEC reports and filings for a discussion of the factors that could cause actual results to differ materially from the forward- looking statements. Given these uncertainties, readers are cautioned not to place undue reliance on the forward-looking statements.*

*The following discussion should be read in conjunction with the audited consolidated financial statements and the notes included in this Report on Form 10-KSB and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in this Report on Form 10-KSB/A.*

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### ITEM 1. BUSINESS

#### Introduction

OXIS International, Inc. (“OXIS” or “the Company”) is a biopharmaceutical/nutraceutical company engaged in the development of research assays, diagnostics, nutraceutical and therapeutic products, which include new technologies applicable to conditions and/or diseases associated with oxidative stress. Oxidative stress is associated with an excess of free radicals, reactive oxygen species (“ROS”), and/or a decrease in antioxidant levels with a resultant development of tissue or organ damage. Oxidative stress can cause tissue injury by triggering cell death or inciting a tissue-damaging inflammatory response. We have invested significant resources to build an early and substantial patent position on both our antioxidant therapeutic technologies and selected oxidative stress assays.

In 1965, Diagnostic Data, Inc. was incorporated in the State of California. The Company changed its incorporation to the State of Delaware in 1972; and changed its name to DDI Pharmaceuticals, Inc. in 1985. In 1994, the Company merged with International BioClinical, Inc. and Bioxytech S.A. and changed its name to OXIS International, Inc. The Company’s principal executive offices and assay manufacturing facilities are located in a 15,000 sq. ft. facility at 6040 N. Cutter Circle, Suite 317, Portland, Oregon 97217.

We market diagnostic assays and fine chemicals to research laboratories and other customers. Our biopharmaceutical and nutraceutical discovery and research efforts are focused on new drugs and compounds to treat diseases associated with tissue damage from free radicals and ROS. We derive revenues primarily from sales of research assays, as well as fine chemicals such as Ergothioneine to researchers and the cosmetics industry. Our diagnostic products include twenty-five assays to measure markers of oxidative stress.

We are pursuing the development of a cardiovascular predictor product intended to provide a more effective diagnostic predictor test for patients at risk of cardiac events before they occur. In 2005, the total economic cost of cardiovascular disease is estimated at \$393 billion by the *Heart Disease and Stroke Statistics, 2005 Update*. Early detection of cardiovascular disease may not only contribute to health and wellness, but also may reduce health care costs. We are developing this product through the combination of our myeloperoxidase assay (“MPO”) with other assays currently in-house (as well as with other assays under development). Our current plan is to submit this product for FDA diagnostic approval and subsequently for commercial launch by the first quarter of 2006. No assurances can be given that this development project will be successful, FDA approval will be obtained, or that a commercially viable product will be successfully launched.

In early 2005, we announced our plans to conduct collaborative research with selective scientists and university laboratories to design an oxidative stress paradigm to diagnose the early onset of potentially fatal human and animal diseases. The initial focus of this study should include the following diseases: Bovine Spongiform Encephalopathy (BSE; Mad Cow Disease); Creutzfeldt Jacob Disease (CJD; human variant of BSE); Type II Diabetes with associated cardiovascular mortality; atherosclerosis and cardiac morbidity; hepatitis with liver failure; and neurodegenerative disorders, such as Alzheimer’s disease and stroke. We intend to attempt to develop diagnostic biomarkers that can identify at an early stage the presence of a disease state, distinguish which patients are most suited for a particular drug, and provide feedback to the physician on how well the drug is working. Our success in building foundations for such collaborative alliances has been limited and we can give no assurances that such relationships will mature or that our efforts to establish oxidative stress paradigms will be successful.

Our lead therapeutic drug candidate, BXT-51072 (based on a small molecular weight antioxidant molecule), completed a Phase IIA clinical trial in inflammatory bowel disease (IBD) in 1999. This Phase IIA trial was a multi-center, nonrandomized, open-label, two-arm study which assessed the safety,

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pharmacokinetics, and efficacy of BXT-51072. Due to the lack of financial resources, we ceased further testing of BXT-51072. Two other therapeutic programs relating to small molecular weight antioxidant molecules are in the pre-clinical stage of development, but we ceased activity with respect to these programs due to the lack of financial resources. We currently do not plan to resume these programs.

Although we ceased further testing of BXT-51072, we continue to review the possibility of further clinical studies. In September 2004, we entered into an exclusive licensing agreement relating to BXT-51072 and related compounds with Haptoguard, Inc. Under the agreement, we have granted the licensee exclusive worldwide rights, in certain defined areas of cardiovascular indications, to develop, manufacture and market BXT-51072 and related compounds from our library of such antioxidant compounds. The licensee is responsible for worldwide product development programs with respect to licensed compounds. We received an upfront license fee of \$450,000, and the licensee must pay royalties to us, as well as additional fees for the achievement of development milestones in excess of \$21 million if all milestones are met and regulatory approvals are granted. There can be no assurances that royalty payments will result or that milestone payments will be realized. The licensee may terminate the agreement for any reason or for no reason by providing us with 180 days' written notice. We have the right to terminate the agreement if the licensee fails to pay us any required payments under the agreement or if the licensee fails to comply with certain plan and timeline requirements relating to the development of the licensed compounds and such failure continues for 30 days after we have given notice to the licensee of such failure. Either party may terminate the agreement upon 30 days' written notice upon certain events relating to the other party's bankruptcy, insolvency, dissolution, winding up or assignment for the benefit of creditors, or upon the other party's uncured breach of any material provision of the agreement. Otherwise, the agreement terminates when our underlying patents related to the licensed compounds expire.

As discussed above, our therapeutic ethical and nutraceutical product portfolio includes three classes of small molecular weight antioxidant molecules. We intend to focus on and intensify our efforts to consummate diagnostic, pharmaceutical and nutraceutical relationships and/or strategic partnerships with larger companies for the purpose of further developing and exploiting our antioxidant molecules. We also intend to file new patent applications related to our current products under development, pursue acquisitions on a selective basis, and expand our marketing efforts in both commercial and research markets. No assurance can be given that our efforts will generate the results anticipated by our management or will in the future be favorable to us.

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### **Government Regulation**

Government regulation in the United States and certain foreign countries today is not currently a significant factor in our business. In the United States, our current products and manufacturing practices are not subject to regulation by the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug and Cosmetic Act as it relates to research products. Development, manufacture and marketing of clinical diagnostic products which we are currently pursuing, as well as therapeutic development, are regulated by the FDA. We believe that we currently are in compliance with all such regulations and intend that in the future all of our diagnostic and therapeutic developments will be in compliance with these regulations.

### **Patents and Trademarks**

We have an extensive portfolio of patents for diagnostic assays and several series of small molecular weight molecules to detect, treat and monitor diseases associated with damage from free radicals and ROS. This portfolio provides opportunities to apply our technologies to a wide range of diseases and conditions of oxidative stress.

Currently, we have approximately 85 currently issued patents or patent applications filed internationally. Patent coverage includes aspects of all three of our classes of small molecular weight antioxidant molecules. We are currently considering whether to abandon certain issued United States and international patents that we deem to be of lesser importance to the strategic direction of the Company, in an effort to preserve our financial resources.

### **Marketing**

We market products and technologies related to oxidative stress. Oxidative stress occurs as a result of an imbalance between damaging free-radicals and related molecules and their inactivation by antioxidants. Oxidative stress can cause tissue injury by triggering cell death or inciting a tissue-damaging inflammatory response.

During 2004, we continued to market our research products to professional scientists in academia, industry and government through our *OXIS*Research catalog. Our marketing program is centered on targeting medical, environmental and various industry audiences interested in oxidative and nitrosative stress (nitrosative stress occurs when the generation of reactive nitrogen species in a system exceeds the system's ability to neutralize and eliminate them). Primary vehicles for this marketing program include printed literature, the *OXIS*Research website and attendance at conferences targeting neuroscience, cancer, cardiac and nutritional researchers, among others.

Our assays for markers of oxidative stress are currently being sold both directly by us and through a network of distributors to researchers primarily in the United States, Europe and the Pacific Rim. We estimate that there are more than 10,000 scientists and clinicians who are working directly in research on free radical biochemistry, and who are potential customers for these research assays. We continue to strengthen our international distribution network by adding selective new distributors around the world. These distributors are exclusively focused on sales of research products in the life science market. In 2004, over 20 distributors represented approximately 45% of our total revenue. Sales to these distributors are at arms length at a negotiated discount from our list price. These distributors are exclusively focused on sales of research products in the life sciences market. Although, to date, we have not recruited distributors of our products, we intend to establish and implement a plan to do so in the future.

During 2004, approximately 11% of our total revenues were from EMD Biosciences, Inc., a distributor customer located in the United States. We expect revenues from sales to EMD Biosciences, Inc. for fiscal year 2005 to be similar to those in 2004.

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### **Products**

**Research Assays.** Revenues from sales of our research diagnostic assays and fine chemicals comprised 81% of total revenues in 2004 and 75% of total revenues in 2003. Certain key products are described below in this subsection. We offer more than 100 research products for sale including:

- Assays for markers of oxidative and nitrosative stress
- Antibodies
- Enzymes
- Controls

We continue to offer a few specialty/proprietary antioxidants and specialty chemicals but product development focus and support are directed at assays, antibodies and enzymes in the area of oxidative and nitrosative stress.

Our primary research product line is comprised of twenty-five assay test kits which measure key markers in free radical biochemistry (markers of oxidative stress). Specifically, these assays measure levels of general and specific antioxidant activity, oxidative alterations to organic lipid, protein and DNA substrates, and pro-oxidant activation of specific white blood cells. Fifteen of our research assays are manufactured at our facility in Portland, Oregon. The others are manufactured pursuant to private label agreements.

These assay kits utilize either chemical (colorimetric) or immunoenzymatic (EIA) reactions that can be read using laboratory spectrophotometers and microplate readers, respectively. We believe our assays offer advantages over conventional laboratory methods, including ease of use, speed, specificity and accuracy.

Our assays for markers of oxidative stress are generally protected by trade secrets, and to some extent, patents. Five U.S. patents and eight international patents have been issued with respect to these assays. The oxidative stress assays are sold under the registered trademark "Bioxytech®."

**Myeloperoxidase (MPO).** We are developing our MPO, a research assay, for sale either alone or in combination with other assays into the diagnostic clinical market. In the fourth quarter of 2003, MPO was used in a study that potentially demonstrates the role of oxidative stress in cardiovascular disease. Currently, biomarkers used for myocardial infarction present significant limitations in predictive quality due to variability of patient population, the range for abnormal test results, and other factors. In contrast, blood plasma MPO levels, as measured by our MPO kit with our own monoclonal antibody, appear to be a better predictor of patients at risk for cardiac events before they occur, according to a report in the New England Journal of Medicine, October 23, 2003. We are pursuing the development of a cardiovascular predictor product, including our MPO assay, combined with other assays currently in-house or under development for FDA diagnostic approval. We have plans for a commercial cardiovascular predictor product by the first quarter of 2006; however, no assurances can be given that the commercial product will be available on such a schedule or that the commercial product will be successful.

**Ergothioneine.** We sell Ergothioneine to selected customers as a compound used in the cosmetics industry. Sales of Ergothioneine were \$87,000 in 2004 and \$333,000 in 2003. Sales during 2003 were principally to one customer in the cosmetics industry in connection with such customer's marketing campaign of a formulation of cosmetics which included, among other things, Ergothioneine. This customer did not purchase in similar quantities in 2004, or in the first quarter of 2005. Although we are not aware of the outcome of the marketing effort concerning the formulation of cosmetics including Ergothioneine, we have not received additional orders from that particular customer or received any indication that additional orders are expected, and we can give no assurances that sales of Ergothioneine to this customer or other cosmetics industry customers will resume.

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**Animal Health Profiling.** During the years 2002 through 2004, we pursued the potential commercial application of several of our assays to the prediction of susceptibility to disease in cattle. From the compiled data a strong and statistically significant relationship between oxidative stress and respiratory disease in cattle had been demonstrated and the beef industry attributes over \$1 billion per year in losses to disease. During this period, we worked extensively with key cattle feeding companies in our attempt to validate and commercialize the use of our test for cattle respiratory disease management. In the fourth quarter of 2004, we concluded from the results of these tests that commercial viability of this program for us was unlikely within a reasonable timeframe and decided we would discontinue funding for this program effective December 31, 2004.

**Bovine Superoxide Dismutase (bSOD).** There were no revenues from sales of bulk bovine SOD (“bSOD”) in 2004 while approximately 21% of our total revenues in 2003 were from sales of bSOD. Commercial-scale manufacture and quality control of bulk bSOD, as well as subsequent quality control and processing of United States Department of Agriculture-inspected edible beef liver into highly purified bulk bSOD requires a complex, multi-step process. With the discovery of several cases of Bovine Spongiform Encephalopathy (“BSE”), commonly known as “mad cow disease,” in the United States and Canada in 2003 and 2004, the use of beef liver as a source for bSOD was no longer possible and the manufacture of this product was discontinued. We do not anticipate this source becoming available again within the foreseeable future and do not anticipate any revenues from sales of this product in the foreseeable future.

### **Competition**

The diagnostic, pharmaceutical and nutraceutical industries are highly competitive. Competition in most of our primary current and potential market areas is intense and expected to increase. There can be no assurance that we can compete successfully.

The main commercial competition at present in our research assay business is represented by, but not limited to, the following companies: Cayman Chemical, Assay Designs and Randox. In addition, our competitors and potential competitors include large pharmaceutical/nutraceutical companies, universities and research institutions. Relative to OXIS, these competitors may have substantially greater capital resources, research and development staffs, facilities, as well as greater expertise manufacturing and making products. In addition, these companies, as well as others, may have or may develop new technologies or use existing technologies that are, or may in the future be, the basis for competitive products.

### **Raw Material Suppliers**

During 2004, we purchased raw materials from three suppliers who comprised 21%, 19% and 18% of the raw materials we purchased. We believe we could readily find alternative suppliers, or that we could readily market alternative products with adequate raw material supply, if necessary. Accordingly, we believe there is limited risk of over reliance on any supplier.

### **Research and Development**

Research and development expenses were \$278,000 and \$409,000 for the years ended December 31, 2004 and 2003, respectively.

We are pursuing the development of a cardiovascular predictor diagnostic product which is intended to provide a better diagnostic predictor test for patients at risk of cardiac events before they occur. We are developing this product through the combination of our MPO assay with other assays currently in-house (as well as with others under development). Our current plans are to submit this product for FDA diagnostic approval and

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subsequently for commercial launch by the first quarter of 2006. No assurances can be given that this development project will be successful, FDA approval will be obtained, or that the commercial product will be successfully launched.

Although we have not adopted a development plan, we will continue to evaluate our therapeutics classes of small molecular weight antioxidant molecules for further development as our financial resources permit. These classes are chemically diverse and represent the major molecules with antioxidant activity present in nature – catalysts, lipid soluble membrane antioxidants and thiols.

In early 2005, we announced our plans to conduct collaborative research with selective scientists and university laboratories to design an oxidative stress paradigm to diagnose the early onset of potentially fatal human and animal diseases. The initial focus of this study should include the following diseases: Bovine Spongiform Encephalopathy (BSE; Mad Cow Disease); Creutzfeld Jacob Disease (CJD; human variant of BSE); Type II Diabetes with associated cardiovascular mortality; atherosclerosis and cardiac morbidity; hepatitis with liver failure; and neurodegenerative disorders, such as Alzheimer's disease and stroke. We intend to attempt to develop diagnostic biomarkers that can identify at an early stage the presence of a disease state, distinguish which patients are most suited for a particular drug, and provide feedback to the physician on how well the drug is working. Our success in building foundations for such collaborative alliances has been limited, and we can give no assurances that such relationships will mature or that our efforts to establish oxidative stress paradigms will be successful.

Our lead therapeutic drug candidate, BXT-51072, completed a Phase IIA clinical trial in inflammatory bowel disease (IBD) in 1999, but due to the lack of financial resources, we ceased further testing of BXT-51072. We continue, however, to review the possibility of further clinical studies. In September 2004, we entered into an exclusive licensing agreement relating to BXT-51072 and related compounds. Under the agreement, we have granted the licensee exclusive worldwide rights, in certain defined areas of cardiovascular indications, to develop, manufacture and market BXT-51072 and related compounds from our library of such antioxidant compounds. The licensee is responsible for worldwide product development programs with respect to licensed compounds. We received an upfront license fee of \$450,000, and the licensee must pay royalties to us, as well as additional fees for the achievement of development milestones in excess of \$21 million if all milestones are met and regulatory approvals are granted. There can be no assurances that royalty payments will result or that milestone payments will be realized.

Much of our future growth would likely depend on potential products that are in research and development and no material revenues have been generated to date from sales of these potential products. No assurance can be given that our product development efforts will be successfully completed, that regulatory approvals will be obtained if required, or that any such products, if developed and introduced, will be successfully marketed. If we do not successfully introduce new products our revenues and results of operations will be materially adversely affected.

### **Employees**

As of December 31, 2004, we had eleven full time employees in the United States. None of our employees are subject to a collective bargaining agreement. We believe our relationship with our employees is good, and we have never experienced an employee-related work stoppage.

We will need to hire and retain a highly-qualified Chief Financial Officer and other executives in order to execute our business plan. No assurance can be given that we will be able to locate and hire such personnel, or that, if hired, we will continue to be able to pay the higher salaries necessary to retain such employees.

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### Foreign Operations and Export Sales

Revenues attributed to countries based on the location of customers:

	2004	2003
Japan	\$221,000	\$333,000
France	\$145,000	\$259,000
United Kingdom	\$ 55,000	\$ 39,000
Korea	\$ 43,000	\$ 67,000
Spain	\$ 37,000	\$596,000
Other foreign countries	\$304,000	\$207,000

The sales to “Other foreign countries” occurred in more than 35 countries, with no single country the site of more than \$35,000 in annual sales.

The decrease in sales to customers in France was primarily the result of decreased Ergothioneine sales (from \$333,000 in 2003 to \$87,000 in 2004). The decrease in sales to customers in Spain was primarily the result of decreased bSOD sales (from \$562,000 in 2003 to zero in 2004).

### ITEM 2. PROPERTIES

The Company occupies, pursuant to leases expiring in November of 2005, office, laboratory and manufacturing space at 6040 N. Cutter Circle, Suite 317, Portland, Oregon. Although the premises currently occupied are suitable and in adequate condition for the Company’s present requirements, the Company believes that other equally suitable premises are readily available.

The Company does not have a real estate investment policy since the Company does not make any such investments.

### ITEM 3. LEGAL PROCEEDINGS

In 1997, the Company completed an offering of its common stock to European investors, and listed the resulting shares on the Nouveau Marché in France. The Company was notified that a Paris lower court (Tribunal de grande instance de Paris) on November 12, 2003, issued an order (the “Order”) requiring the Company (i) to file its 2002 Document de Reference (“2002 Reference Document”) as required under French law and the regulations of the Autorité des Marchés Financiers (the “AMF”), the French regulatory agency overseeing the Nouveau Marché, within eight days of the court’s Order (“filing deadline”) and (ii) if the Company has not filed with the AMF its 2002 Reference Document by the filing deadline, to pay a fine of 1,500 Euro for each day until it files its 2002 Reference Document with the AMF. Following the issuance of the Order, the Company (1) filed its 2002 Reference Document with the AMF and received written confirmation that its 2002 Reference Document has been registered and (2) appealed the Order to the extent that it imposed fines on the Company. The Company has since dismissed its appeal of the Order, and during the first quarter of 2004 paid approximately \$11,600 in settlement of any obligation to pay fines under the Order.

The AMF also engaged in a separate investigation relating to the Company’s failing to file financial and other disclosure information as required under French law from 1999 through 2002 (the “Investigation”). At a hearing before the Disciplinary Commission of the AMF on June 17, 2004 the Disciplinary Commission considered a report of the AMF investigator recommending that the Disciplinary Commission impose a fine of not less than 100,000 Euro. Following the hearing, the Disciplinary Commission ordered the Company to pay a

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fine of 50,000 Euro (approximately \$62,000) with respect to the Company's failure to file financial and other disclosure information as required under French law from 1999 through 2002. The Company did not appeal this order and the fine has been paid. As of December 31, 2004, the Company has recorded approximately \$183,000 related to the defense and settlement of this investigation, including foreign legal expenses of \$121,000 and fines imposed by the AMF of \$62,000. These charges are recorded as a separate line item under Operating Expenses.

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

No matter was submitted during the fourth quarter of 2004 to a vote of security holders, through solicitation or proxies or otherwise.

**PART II**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON STOCK AND RELATED SHAREHOLDER MATTERS**

The Company's common stock continues to be traded in the Over-The-Counter Bulletin Board and remains listed in France on the Nouveau Marche.

The quotations are reflective on inter-dealer prices, without retail markup, markdown or commission and may not represent actual transactions. Previous quarterly high and low sales prices of the Company's common stock on the over-the-counter board are as follows:

	2004				2003			
	4th	3rd	2nd	1st	4th	3rd	2nd	1st
High	\$0.65	\$0.69	\$0.84	\$0.90	\$0.78	\$0.51	\$0.58	\$0.28
Low	\$0.41	\$0.32	\$0.45	\$0.52	\$0.20	\$0.22	\$0.12	\$0.12

The Company has an estimated 5,500 shareholders, including approximately 3,000 shareholders who hold their shares in street name. The Company utilizes its assets to develop its business and, consequently, has never paid a dividend and does not expect to pay dividends in the foreseeable future.

On March 7, 2002, the Company consummated the sale of 1.5 million shares of its Series F preferred stock to Meridian Financial Group L.L.P. ("Meridian") at a price of \$1 per share, paid in cash. Each share of Series F preferred stock was initially convertible into ten (10) shares of the Company's common stock. As part of the sale, the Company also issued a warrant granting Meridian the right to purchase up to 1.5 million shares of common stock at \$1.00 per share. In June 2003, Meridian converted its shares of Series F preferred stock into 15,000,000 shares of the Company's common stock and distributed such shares, and the 1,500,000 warrants, to its members/investors and to Triax Capital Management, Inc. ("Triax") as managing member. Triax in turn distributed its shares of the Company's Common Stock allocated to it as its managing member to its shareholders.

During July 2003, the board of directors of the Company offered all holders of warrants a reduced exercise price for a limited period of time. The exercise price for these warrants was reduced to \$0.20 per shares, and maturity date for 598,449 warrants issued in 1998 was extended to August 11, 2003. The exercise price for these warrants was previously \$1.00 per share. All warrants issued prior to July 1998 had lapsed and were not affected by this board action. The decrease of exercise price did not result in any change to the outstanding value of the warrants. Pursuant to the offered reduced exercise price, a total of 1,133,000 warrants were exercised at an aggregate purchase price of \$226,600. As part of the offer, with each share of stock issued one new warrant was issued having a \$1.00 exercise price and a two-year life.

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On January 14, 2004, the Company completed a private placement of securities, pursuant to which (i) certain bridge loan investors (“Note Holders”) paid to the Company \$570,000 in the aggregate, (ii) the Company issued promissory notes (“Notes”) due on the first anniversary date of issuance or immediately on an acquisition, bearing 7% interest per annum, to the investors in principal amount of \$570,000 in the aggregate, which promissory notes are convertible in due course into Company common stock at a rate of one share for each \$0.40 of principal and interest outstanding (the “Conversion Price”), or in the Event of Default (as defined in the Notes) by the Company, into Company common stock at a rate of one share for each \$0.15 of principal and interest outstanding, and (iii) the Company issued warrants to the investors, exercisable for up to 712,500 shares of common stock at an exercise price of \$0.50 per share.

On December 30, 2004, the Company received notices from each of the Note Holders electing under the terms of such Notes to convert all debt under the Notes plus related accrued interest into an aggregate of 1,520,932 shares of Common Stock of the Company. In connection with the Note Holders to election to convert such debt, the Company agreed to issue to the Note Holders warrants exercisable for a period of five years for the purchase of up to an aggregate of 760,469 shares of the common stock of the Company at an exercise price of \$1.00 per share.

The private placement of the securities to Note Holders was exempt from registration under the Securities Act, pursuant to Section 4(2) thereof, and Rule 506 promulgated by the SEC under the Securities Act.

Throughout the first ten weeks of 2004, Axonyx acquired approximately 52.4% of our outstanding voting stock. Axonyx’s holdings subsequently were decreased to approximately 34% following a private placement of equity at December 30, 2004.

On March 10, 2004, in connection with such acquisition by Axonyx of our common stock, three of the Company’s directors resigned from our Board of Directors and the Board appointed four directors that had been nominated by Axonyx. Three of these directors have subsequently resigned. In June 2004, the Company’s Chief Executive Officer retired and was replaced by an Acting Chief Operating Officer. In August 2004, the Company’s Chief Financial Officer resigned. While we had interim Chief Executive Officers in place, we deferred the hiring of other senior management personnel to allow a newly-engaged full time Chief Executive Officer to assist in the selection and training of such key personnel. We have succeeded in engaging Steven T. Guillen as our Chief Executive Officer, and will endeavor to find suitable new candidates for the position Chief Financial Officer and other key management positions within the Company.

On December 30, 2004, the Company entered into definitive agreements with investors relating to the private placement of \$6.5 million of its securities through the sale of 12,264,158 shares of its common stock at \$0.53 per share. On January 6, 2005, the Company and the investors closed the private placement transaction. The transaction resulted in the issuance on or about January 10, 2005 of 12,264,158 shares of the Company’s common stock for which the Company has received gross proceeds of \$0.53 per share. In addition, on January 6, 2005, the Company issued to the purchasers in the private placement transaction warrants to purchase an additional 12,264,158 shares of the common stock of the Company, 50% at an exercise price of \$0.66 per share and 50% at an exercise price of \$1.00 per share.

Upon the closing of the private placement transaction, as partial consideration for services rendered as the placement agent for the private placement transaction, the Company issued to Rodman & Renshaw, LLC a warrant to purchase 306,604 shares of Common Stock of the Company at an exercise price of \$0.66 per share and a warrant to purchase 306,604 shares of Common Stock of the Company at an exercise price of \$1.00 per share.

The offer, sale and issuance of securities to the purchasers in the private placement was exempt from registration under the Securities Act, pursuant to Section 4(2) thereof, and Rule 506 promulgated by the SEC under the Securities Act.

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The following is a summary of the Company's equity compensation plans at December 31, 2004:

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</u>	<u>Weighted- average exercise price of outstanding options, warrants and rights (b)</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)</u>
Equity compensation plan approved by security holders	3,924,972	\$ 0.84	2,160,531
Equity compensation plan not approved by security holders	747,888	\$ 0.27	—
<b>Total</b>	<b>4,672,860</b>		<b>2,160,531</b>

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**ITEM 6. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the financial statements and related notes. This discussion contains forward-looking statements based upon our current expectations and involves risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth in “Risks Related to Our Business,” “Business” and elsewhere in this document. See the paragraphs following the heading “Forward-Looking Statements” for additional discussion.

**General**

The Company is a biopharmaceutical/nutraceutical company engaged in the development of research assays, diagnostics, nutraceutical and therapeutic products, which include new technologies applicable to conditions and/or diseases associated with oxidative stress.

We market diagnostic assays and fine chemicals to research laboratories and other customers. Our biopharmaceutical and nutraceutical discovery and research efforts are focused on new drugs and compounds to treat diseases associated with tissue damage from free radicals and ROS. We derive revenues primarily from sales of research assays, as well as fine chemicals such as Ergothioneine to researchers and the cosmetics industry. Our diagnostic products include twenty-five assays to measure markers of oxidative stress.

Our current plans include a new focus on the areas of clinical cardiac predictor testing, biomarker research and the nutraceutical marketplace. We are pursuing the development of a cardiovascular predictor product intended to provide a more effective diagnostic predictor test for patients at risk of cardiac events before they occur. We are developing this product through the combination of our MPO assay with other assays currently in-house (as well as with other assays under development). Our current plan is to submit this product for FDA diagnostic approval and subsequently for commercial launch by the first quarter of 2006.

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In early 2005, we announced our plans to conduct collaborative research with selective scientists and university laboratories to design an oxidative stress paradigm to diagnose the early onset of potentially fatal human and animal diseases. We intend to attempt to develop diagnostic biomarkers that can identify at an early stage the presence of a disease state, distinguish which patients are most suited for a particular drug, and provide feedback to the physician on how well the drug is working.

We also believe that our Ergothioneine compound may be well suited for development as a nutraceutical supplement that can be sold over the counter and we intend to pursue the development of Ergothioneine for use in such markets.

Additional capital that will be allocated to fund these plans was received in the form of a private placement of equity on December 30, 2004, in the amount of \$4,250,000 and an additional \$2,250,000 in early January 2005. We believe that these funds will allow the Company to continue operating in accordance with its current plans for 2005. However, if we determine to engage in further development and commercialization programs with respect to our antioxidant therapeutic technologies, oxidative stress assays, or other currently unidentified opportunities, additional capital may be required.

Throughout the first ten weeks of 2004, Axonyx acquired approximately 52.4% of our outstanding voting stock. Axonyx's holdings subsequently were decreased to approximately 34% following a private placement of equity at December 30, 2004.

On March 10, 2004, in connection with such acquisition by Axonyx of our common stock, three of the Company's directors resigned from our Board of Directors and the Board appointed four directors that had been nominated by Axonyx. Three of these directors have subsequently resigned. In June 2004, the Company's Chief Executive Officer retired and was replaced by an Acting Chief Operating Officer. In August 2004, the Company's Chief Financial Officer resigned. While we had interim Chief Executive Officers in place, we deferred the hiring of other senior management personnel to allow a newly-engaged full time Chief Executive Officer to assist in the selection and training of such key personnel. We have succeeded in engaging Steven T. Guillen as our Chief Executive Officer, and will endeavor to find suitable new candidates for the position Chief Financial Officer and other key management positions within the Company.

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### **Critical Accounting Policies**

Management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. Our critical accounting policies are described in Note 2 of the Company's Consolidated Financial Statements. This summary of critical accounting policies of the Company is presented to assist in understanding the Company's financial statements. All accounting estimates are at risk to change because of internal and external factors, and when adjustments are adopted. Most of our estimates are based upon historically known data and have remained stable over time. Certain estimates are subject to market place conditions, and are discussed below.

On an ongoing basis, management evaluates its estimates, including those related to impairment of long-lived assets, including finite lived intangible assets, accrued liabilities and certain expenses. We base our estimates on historical experience and on various other assumptions that we believe 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 materially from these estimates under different assumptions or conditions.

We believe the following critical accounting estimates and policies, among others, involve the more significant judgments and estimates used in the preparation of our financial statements.

*Intellectual Property License Fees* – We recognize license fee revenue for licenses to the Company's intellectual property when earned under the terms of the agreements. Generally, revenue is recognized upon transfer of the license unless we have continuing obligations for which fair value cannot be established, in which case the revenue is recognized over the period of the obligation. We consider all arrangements with payment terms extending beyond twelve months not to be fixed or determinable. In certain licensing arrangements, there is a minimum guarantee recognized upon transfer of the license when collectibility is reasonably assured, unless we have continuing obligations for which fair value cannot be established and the amount of the variable fee is in excess of the guaranteed minimum recognized as revenue.

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*Inventories* – Inventories are stated at the lower of cost to purchase and/or manufacture the inventory or the current estimated market value of the inventory. We regularly review our inventory quantities on hand and record a provision for excess and obsolete inventory based primarily on our estimated forecast of product demand and/or our ability to sell the products and production requirements. Demand for our products can fluctuate significantly. Factors which could affect demand for our products include unanticipated changes in consumer preferences, general market conditions or other factors, which may result in cancellations of advance orders or a reduction in the rate of reorders placed by customers and/or continued weakening of economic conditions. Additionally, our estimates of future product demand may be inaccurate, which could result in an understated or overstated provision required for excess and obsolete inventory. Our estimates are based upon our understanding of historical relationships which can change at anytime.

*Product sales* – We manufacture, or have manufactured on a contract basis, products that are sold to customers. We recognize revenue from sales when there is persuasive evidence that an arrangement exists, services have been rendered, the seller's price to a buyer is determinable, and collectibility is reasonably assured. The Company's mix of product sales are substantially at risk to market conditions and demand, which may change at anytime.

*Patents and trademarks* – Our patents and trademarks are stated at cost. The recoverability of patents and trademarks is reevaluated each year based upon management's expectations relating to the life of the technology and current competitive market conditions. As of December 31, 2004 and 2003, we have recorded \$77,000 and \$65,000 in amortization expense, respectively, related to our patents, patents pending and trademarks. We are amortizing these costs over the life of the respective patents or trademarks.

*Inflation* – We do not believe that inflation had a significant impact on our results of operations for the periods presented.

## **Results of Operations**

### *Revenues*

Our revenues for the past two years consisted of the following:

	<u>2004</u>	<u>2003</u>
Research assays and fine chemicals	\$1,914,000	\$2,056,000
Medical instruments	—	12,000
Bovine Superoxide Dismutase ("bSOD") for research and human use	—	562,000
Other	450,000	110,000
	<u>          </u>	<u>          </u>
Total sales	<u>\$2,364,000</u>	<u>\$2,740,000</u>

In 2004, sales of research assays and fine chemicals decreased by \$142,000 to \$1,914,000, a 7% decrease over the 2003 sales of \$2,056,000. This decrease is due primarily to decreased sales volumes of Ergothioneine (\$246,000) which reflects a lower level of orders received from our customers who are principally in the cosmetics industry. This decrease was partially offset by increased research assay sales volumes. Sales during 2003 were principally to one customer in the cosmetics industry in connection with such customer's marketing campaign of a formulation of cosmetics which included, among other things, Ergothioneine. This customer did not purchase in similar quantities in 2004, or in the first quarter of

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2005. Although we are not aware of the outcome of the marketing effort concerning the formulation of cosmetics including Ergothioneine, we have not received additional orders from that particular customer or received any indication that additional orders are expected, and we can give no assurances that sales of Ergothioneine to this customer or other cosmetics industry customers will resume.

Revenue from medical instruments in 2003 was derived from an inventory purchase and royalty agreement entered into in 2001. This agreement terminated in 2003, and no further revenue will be generated from this agreement. This included all transactions and activity for medical instruments.

There were no revenues from sales of bulk bovine SOD ("bSOD") in 2004 while approximately 21% of our total revenues in 2003 were from sales of bSOD. Commercial-scale manufacture and quality control of bulk bSOD, as well as subsequent quality control and processing of United States Department of Agriculture-inspected edible beef liver into highly purified bulk bSOD requires a complex, multi-step process. With the discovery of several cases of Bovine Spongiform Encephalopathy ("BSE"), commonly known as "mad cow disease," in the United States and Canada in 2003 and 2004, the use of beef liver as a source for bSOD was no longer possible and the manufacture of this product was discontinued. We do not anticipate this source becoming available again within the foreseeable future and do not anticipate any revenues from sales of this product in the foreseeable future.

Other revenue during 2004 represents an exclusive license agreement resulting in the Company recognizing \$450,000 in license revenue in the third quarter of 2004. There can be no assurances that future milestone events and payments will be realized under the exclusive license agreement or that we may be able to enter into additional future license agreements. Other revenue during 2003 was primarily a royalty payment for a previously licensed technology which made its last payment during 2003.

### *Costs and Expenses*

Cost of revenue (sales) for research products increased by 9% to 64% in 2004 due to changes in the product mix of our sales. Sales of research assays increased by \$82,000 over 2003 but Ergothioneine sales were lower by \$246,000 compared to 2003 and there were no sales bSOD in 2004 with \$562,000 of bSOD sales in 2003. In addition, we incurred extra cost from adding product support personnel and made other personnel changes in 2004.

Gross profit for 2004 was \$1,148,000, compared to \$1,244,000 during 2003. Gross Profit from product revenues, exclusive of license fees, was \$698,000, or 36% of product revenues, compared to \$1,244,000, or 45% of product revenues during 2003. The decrease in gross profit results primarily from lower product sales revenue. This decrease was partially offset by license fee revenues of \$450,000, as discussed in "Revenues" above for which no costs are associated.

Research and development costs decreased to \$278,000 in 2004 from \$409,000 in 2003, a decrease of \$131,000, primarily as a result of a reduction in research and development activity by our health products (\$68,000) and therapeutic (\$65,000) areas as necessitated by our lack of capital. Research and development expense as a percentage of product revenues were 15% in 2004 as compared to 15% in 2003.

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Research and development expense is expected to increase significantly in the coming year due to the cost of developing the cardiac predictor program.

In 2004, sales, general and administrative expenses increased by \$195,000, from \$1,648,000, or 60% of product revenues in 2003 to \$1,843,000, or 96% of product revenues, in 2004. This increase is primarily due to expenses related to the increased spending in the cardiac predictor program and the animal health profiling program partially offset by reduced expenses from the retirement of our Chief Executive Officer in June 2004 and resignation of our Chief Financial Officer in August 2004. These positions have not yet been filled by full-time employees. We do not anticipate further funding of our animal health profiling program beyond December 31, 2004.

Foreign legal proceedings during 2004 of \$183,000 are related to the AMF proceedings including legal expenses of \$121,000 and fines imposed by the AMF of \$62,000 as described above in Note 14 to the financial statements contained herein which are not expected to be recurring expenses. Such proceedings have concluded.

Restructuring charges during 2004 of \$605,000 are related to the Axonyx change of control including legal (\$196,000), management consulting (\$34,000), travel (\$8,000), executive search (\$22,000) and severance expenses (\$345,000) which are not expected to be recurring expenses.

### *Financing Fees*

We paid finders' fees and professional fees of approximately \$85,000 in connection with the closing of a \$570,000 convertible bridge loan financing on January 14, 2004. These fees were amortized over the life of the loan. Total amortization of the debt discount on the convertible bridge loans and the related fees were approximately \$654,000 for 2004. In connection with the noteholders' conversion of their notes to common stock in December 2004, we issued 760,469 new warrants with a related expense of \$202,000.

### *Interest Expense*

Interest expense was \$101,000 for the year ended December 31, 2004 resulting primarily from the interest incurred by the short-term bridge financing and the Axonyx loan.

### *Other Income*

During the first quarter of 2003, we sold our equity interest in Caprius Inc., resulting in other income of \$8,000.

We expect to have smaller losses in 2005 but can give no assurance as to when and if we will become profitable. These losses and expenses may increase and fluctuate from quarter to quarter as we expand our development activities. There can be no assurance that we will achieve profitable operations.

## **Liquidity and Capital Resources**

The Company, on a consolidated basis, had cash and cash equivalents of \$4,687,000 and \$372,000 at December 31, 2004 and 2003, respectively.

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The Company's principal sources of cash during the last two years have originated with the sale of equity instruments. In December 2004, the Company raised \$4,250,000 in cash and \$2,250,000 in receivables (which were converted to cash in early January 2005) from the private placement of 12,877,364 shares of common stock and an equivalent number of common stock warrants. This equity transaction enabled the Company to have a total of \$4,687,000 in cash at year-end 2004. By contrast, in 2003 the Company's cash proceeds from equity transactions were \$226,000, which came from the exercise of warrants, and \$21,000 from the exercise of stock options.

In 2004, the Company's secondary sources of cash were short-term borrowings of \$1,686,000. The Company had no long-term borrowings in 2004, and no long-term or short-term borrowing proceeds in 2003.

The Company's principal uses of cash during 2004 and 2003 were the Company's losses from operations of \$1,761,000 and \$813,000, respectively. While the Company's gross profit and major operating expenses were comparable for 2003 and 2004, the 2004 loss from operations contained two unusual categories of expense not present in 2003: management restructuring charges of \$605,060 and \$183,000 of foreign legal proceedings relating to the Nouveau Marché in France. These two unusual expenses are the major cause of 2004's increased operating loss from the prior year.

The Company's net loss in 2004 also reflected larger borrowing costs than 2003. Interest expense and financing fees aggregating \$957,000 in 2004 greatly exceeded the 2003 borrowing costs (interest only) of \$14,000.

While the Company's principal uses of cash were net operating losses and the secondary uses of cash were borrowing costs, to a smaller extent the Company's uses of cash also included purchases of patents and equipment totaling \$309,000 in 2004 and \$160,000 in 2003.

We believe we have sufficient capital resources to sustain our operations for at least eighteen (18) months. However, if we determine to engage in further development and commercialization programs with respect to our antioxidant therapeutic technologies, oxidative stress assays or other currently unidentified opportunities additional capital may be required.

### *Net Loss*

We incurred net losses in 2004 and 2003, and we expect smaller losses in the future but can not predict profitability in the foreseeable future. Our net loss increase of \$1,880,000 to \$2,698,000 is due primarily to expenses relating to foreign legal proceedings (\$183,000); restructuring charges (\$605,000) and the expenses related to short-term bridge financing (\$654,000) and costs associated with warrants issued for the conversion of the bridge loans (\$202,000).

We expect to incur a net loss for 2005 and believe we have sufficient funding to sustain our operations through 2005.

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### *Commitments and Contingencies*

The Company leases its facilities in Oregon under an operating lease that expires in November 2005. Minimum lease payments to which the Company is committed is \$122,000 in 2005.

## **RISK FACTORS**

### **Risks Related to Our Business**

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. The following discussion highlights some of these risks and others are discussed elsewhere in this Report on Form 10-KSB/A.

*We will need additional financing in order to complete our development and commercialization programs.*

As of March 31, 2005, we had an accumulated deficit of approximately \$62,519,000. We currently do not have sufficient capital resources to complete the development and commercialization of our antioxidant therapeutic technologies and oxidative stress assays, and no assurances can be given that we will be able to raise such capital in the future on terms favorable to us, or at all. The unavailability of additional capital could cause us to cease or curtail our operations and/or delay or prevent the development and marketing of our potential products. In addition, we may choose to abandon certain issued United States and international patents that we deem to be of lesser importance to our strategic direction, in an effort to preserve our financial resources.

Our future capital requirements will depend on many factors including the following:

- continued scientific progress in our research and development programs and the commercialization of additional products;
- the cost of our research and development and commercialization activities and arrangements, including sales and marketing;
- the costs associated with the scale-up of manufacturing;
- the success of pre-clinical and clinical trials;
- the establishment of and changes in collaborative relationships;
- the time and costs involved in filing, prosecuting, enforcing and defending patent claims;
- the time and costs required for regulatory approvals;
- technological competition and market developments; and
- the cost of complying with the requirements of the AMF in France.

We have not determined whether we will attempt to raise additional capital within the next twelve to eighteen months to fund certain development and commercialization programs. We believe that our current capital resources are sufficient to sustain operations and our development programs with respect to our cardiovascular predictor product, diagnostic biomarkers and Ergothioneine as a nutraceutical supplement. We have granted a licensee exclusive worldwide rights, in certain defined areas of cardiovascular indications, to develop, manufacture and market BXT-51072 and related compounds from our library of such antioxidant compounds. The licensee is responsible for worldwide product development programs with respect to licensed compounds. Due to the lack of financial resources, we ceased further testing of BXT-51072 but continue to

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review the possibility of further developing applications for BXT-51072 and related compounds outside of the areas defined in the license. However, further development and commercialization of antioxidant therapeutic technologies, oxidative stress assays or currently unidentified opportunities may require additional capital. The fact that further development and commercialization of a product or technology would require us to raise additional capital, would be an important factor in our decision to engage in such further development or commercialization. No assurances can be given that we will be able to raise such funds in the future on terms favorable to us, or at all.

*We may experience disruption or may fail to achieve any benefits in connection with the recent changes in executive management and in Board membership.*

During the second quarter of 2004, our former Chief Executive Officer retired, and during the third quarter of 2004 our Chief Operating and Financial Officer left the employment of the Company. As a result, others who had limited experience with the Company were appointed to serve as acting Chief Executive Officer, acting Chief Operating Officer and acting Chief Financial Officer. The acting Chief Financial Officer is also the Chairman of the Board of Directors and is serving in such capacities without cash compensation and without an employment agreement. One of these individuals, Gosse Bruinsma, then a director of the Company, received 100,000 additional stock options that were reported in the financial statements in accordance with APB No. 25. Note 2 of the financial statements contains pro forma disclosure required by SFAS No. 123 valuing these options at \$47,260. On February 28, 2005, the Board appointed Steven T. Guillen to the positions of President and Chief Executive Officer of the Company, and as a member of our Board. In addition, during 2004 and early 2005, following the acquisition of a then-majority interest in the Company by Axonyx, eight directors have resigned from the Board resulting in a four person Board. Three out of the four directors currently serving on the Board commenced their service on the Board during 2004 or 2005.

One impact of such changes in our officers and directors has been to delay our sales promotions in the research assay market and in development of Ergothioneine market opportunities. Further, we narrowed our strategic focus to concentrate resources, including discontinuing the Animal Health Profiling program. There can be no assurances that these changes will not cause further disruptions in, or otherwise adversely affect, our business and results of operations.

*If we fail to attract and retain key personnel, our business could suffer.*

Our future depends, in part, on our ability to attract and retain key personnel. We may not be able to hire and retain such personnel at compensation levels consistent with our existing compensation and salary structure. While we had interim Chief Executive Officers in place, we deferred the hiring of other senior management personnel to allow a newly-engaged full time Chief Executive Officer to assist in the selection and training of such key personnel. While we have succeeded in engaging Steven T. Guillen as our Chief Executive Officer, we cannot predict whether we will be successful in finding suitable new candidates for the position Chief Financial Officer and other key management positions within the Company. While we have entered into a letter agreement of employment with Mr. Guillen, he is free to terminate his employment "at will." Further, we cannot predict whether Mr. Guillen will be successful in his new role as our Chief Executive Officer, or whether senior management personnel hires will be effective. The loss of services of executive officers or key personnel, any transitional difficulties with our new Chief Executive Officer or the inability to attract qualified personnel could have a material adverse effect on our financial condition and business. The Company does not have any key employee life insurance policies with respect to any of its officers.

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*The success of our business depends upon our ability to successfully develop and commercialize products.*

We cannot assure you that our efforts to develop and commercialize a cardiac predictor product, diagnostic biomarkers, an Ergothioneine nutraceutical product or any other products will be successful. The cost of such development and commercialization efforts can be significant and the likelihood of success of any such programs is difficult to predict. The failure to develop or commercialize such new products could be materially harmful to us and our financial condition.

*Our future profitability is uncertain.*

We cannot predict our ability to reduce our costs or achieve profitability. Our research and development expenses are expected to increase as we attempt to develop potential products. As evidenced by the substantial net losses during 2004, losses and expenses may increase and fluctuate from quarter to quarter. There can be no assurance that we will ever achieve profitable operations. We believe we have sufficient cash resources to sustain our operations for at least eighteen months. However, if we determine to engage in further development and commercialization programs with respect to our antioxidant therapeutic technologies, oxidative stress assays or other currently unidentified opportunities, additional capital may be required.

*We have no biopharmaceutical or clinical diagnostic products available for sale and we may never be successful in developing products suitable for commercialization.*

All of our biopharmaceutical and clinical diagnostic candidates are at an early stage of development and all of such therapeutic and clinical diagnostic candidates will require expensive and lengthy testing and regulatory clearances. None of our therapeutic or clinical diagnostic candidates have been approved by regulatory authorities. We have no therapeutic or clinical diagnostic products available for sale and we may not have any products commercially available for several years, if at all. There are many reasons that we may fail in our efforts to develop our therapeutic and clinical diagnostic candidates, including:

- our therapeutic and clinical diagnostic candidates may be ineffective, toxic or may not receive regulatory clearances,
- our therapeutic and clinical diagnostic candidates may be too expensive to manufacture or market or may not achieve broad market acceptance,
- third parties may hold proprietary rights that may preclude us from developing or marketing our therapeutic and clinical diagnostic candidates, or
- third parties may market equivalent or superior products.

*Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we cannot accurately predict the timing and level of such expenses.*

Our future success may depend in part upon the results of clinical trials designed to assess the safety and efficacy of our potential products. We do not have substantial experience in developing and running clinical trials. The completion of clinical trials often depends significantly upon the rate of patient enrollment, and our expense levels will vary depending upon the rate of enrollment. In addition, the length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly and is difficult to predict. The expenses associated with each phase of development depend upon the design of the trial. The design of each phase of trials depends in part upon results of prior phases, and additional trials may be needed at each phase. As a result the expense associated with future phases cannot be predicted in advance. Further, if we undertake clinical trials, we may decide to terminate or suspend ongoing trials. Failure to comply with extensive FDA regulations may result in unanticipated delay, suspension or cancellation of a trial or the

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FDA's refusal to accept test results. The FDA may also suspend our clinical trials at any time if it concludes that the participants are being exposed to unacceptable risks. As a result of these factors, we cannot predict the actual expenses that we will incur with respect to trials for any of our potential products, and we expect that our expense levels will fluctuate unexpectedly in the future.

*Competition in most of our primary current and potential market areas is intense and expected to increase.*

The diagnostic, pharmaceutical and nutraceutical industries are highly competitive. The main commercial competition at present in our research assay business is represented by, but not limited to, the following companies: Cayman Chemical, Assay Designs and Randox. In addition, our competitors and potential competitors include large pharmaceutical/nutraceutical companies, universities and research institutions. Relative to OXIS, these competitors may have substantially greater capital resources, research and development staffs, facilities, as well as greater expertise manufacturing and making products. In addition, these companies, as well as others, may have or may develop new technologies or use existing technologies that are, or may in the future be, the basis for competitive products. There can be no assurance that we can compete successfully.

In addition, current and potential competitors may make strategic acquisitions or establish cooperative relationships among themselves or with third parties, thereby increasing the ability of their products to address the needs of our current and prospective customers. Accordingly, it is possible that new competitors or alliances among current and new competitors may emerge and rapidly gain significant market share. Such competition could materially adversely affect our ability to commercialize existing technologies or new technologies on terms favorable to us. Further, competitive pressures could require us to reduce the price of our products and technologies, which could materially adversely affect our business, operating results and financial condition. We may not be able to compete successfully against current and future competitors and any failure to do so would have a material adverse effect upon our business, operating results and financial condition.

*Axonyx holds the voting power to control matters affecting us.*

Axonyx owns approximately 33.8% of our issued and outstanding stock. In addition, Marvin Hausman, the Chairman of the Board of Axonyx is the Chairman of the Board and acting Chief Financial Officer of the Company, and S. Colin Neill, the Chief Financial Officer of Axonyx, is a member of the Board of Directors and Secretary of the Company. Given these circumstances, Axonyx may influence our business direction and policies, and, thus, may have the ability to control certain material decisions affecting us. In addition, such concentration of voting power could have the effect of delaying, deterring or preventing a change of control or other business combination that might otherwise be beneficial to our shareholders. Section 203 of the Delaware General Corporation Law prohibits a Delaware corporation from engaging in any business combination with any interested shareholder for a period of three years unless the transaction meets certain conditions. Section 203 also limits the extent to which an interested shareholder can receive benefits from our assets. These provisions could complicate or prohibit certain transactions (including a financing transaction between the Company and Axonyx), or limit the price that other investors might be willing to pay in the future for shares of our common stock.

*If we are unable to develop and maintain alliances with collaborative partners, we may have difficulty developing and selling our products and services.*

Our ability to realize significant revenues from new products and technologies is dependent upon, among other things, our success in developing business alliances and licensing arrangements with

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nutraceutical/biopharmaceutical and/or health related companies to develop and market these products. To date, we have had limited success in establishing foundations for such business alliances and licensing arrangements and there can be no assurance that our efforts to develop such business relationships will progress to mature relationships or that any such relationships will be successful. Further, relying on these or other alliances is risky to our future success because:

- our partners may develop products or technologies competitive with our products and technologies;
- our partners may not devote sufficient resources to the development and sale of our products and technologies;
- our collaborations may be unsuccessful; or
- we may not be able to negotiate future alliances on acceptable terms.

*Our revenues and quarterly results have fluctuated historically and may continue to fluctuate, which could cause our stock price to decrease.*

Our revenues and operating results may fluctuate due in part to factors that are beyond our control and which we cannot predict. Material shortfalls in revenues will materially adversely affect our results and may cause us to experience losses. In particular, our revenue growth and profitability depend on sales of our research assays and fine chemicals. Factors that could cause sales for these products and other products to fluctuate include:

- an inability to produce products in sufficient quantities and with appropriate quality;
- an inability to obtain sufficient raw materials;
- the loss of or reduction in orders from key customers;
- variable or decreased demand from our customers;
- the receipt of relatively large orders with short lead times;
- our customers' expectations as to how long it takes us to fill future orders;
- customers' budgetary constraints and internal acceptance review procedures;
- the fact that there may be only a limited number of customers that are willing to purchase our research assays and fine chemicals;
- a long sales cycle that involves substantial human and capital resources; and
- potential downturns in general or in industry specific economic conditions.

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Each of these factors has impacted, and may in the future impact, the demand for and availability of our products and our quarterly operating results. For example, due to the unavailability of beef liver as a source for bSOD we were unable to sell any bSOD during 2004, as compared to sales of \$562,000 in 2003. We do not anticipate this source becoming available again within the foreseeable future and do not anticipate any revenues from sales of this product in the foreseeable future. In addition, a decrease in the demand for our Ergothioneine product resulted in a reduction of sales to \$87,000 in 2004, compared to \$333,000 in 2003. We cannot predict with any certainty our future sales of Ergothioneine.

If the sales or development cycles for research assays and fine chemicals lengthen unexpectedly, our revenues may decline or not grow as anticipated and our results from operations may be harmed.

*Changes in accounting standards regarding stock option plans could increase our reported losses, cause our stock price to decline and limit the desirability of granting stock options.*

The Financial Accounting Standards Board has issued regulations that eliminate the ability to account for share-based compensation transactions using the intrinsic method that we currently use and generally would require that such transactions be accounted for using a fair-value-based method and recognized as an expense in our consolidated statement of operations. As currently contemplated, we will be required to expense stock options after January 1, 2006. Currently, we generally only disclose such expenses on a pro forma basis in the notes to our consolidated financial statements in accordance with accounting principles generally accepted in the United States. Expensing such stock options will add to our losses or reduce our profits, if any. In addition, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program.

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*Our income may suffer if we receive relatively large orders with short lead times, or our manufacturing capacity does not otherwise match our demand.*

Because we cannot immediately adapt our production capacity and related cost structures to rapidly changing market conditions, when demand does not meet our expectations, our manufacturing capacity will likely exceed our production requirements. Fixed costs associated with excess manufacturing capacity could adversely affect our income. Similarly, if, we receive relatively large orders with short lead times, we may not be able to increase our manufacturing capacity to meet product demand, and, accordingly, we will not be able to fulfill orders in a timely manner. During a market upturn, we may not be able to purchase sufficient supplies to meet increasing product demand. In addition, suppliers may extend lead times, limit supplies or increase prices due to capacity constraints or other factors. These factors could materially and adversely affect our results.

*We depend on a single supplier for our bSOD product and we do not expect to be able to maintain sales of our bSOD product due to the lack of availability of raw material. Future availability or a new formulation of this raw material is unknown at this time.*

We depend on a single supplier, Diosynth in the Netherlands, to provide bovine Superoxide Dismutase (bSOD) in required volumes, and at appropriate quality and reliability levels. With the discovery of several cases of Bovine Spongiform Encephalopathy (“BSE”), commonly known as “mad cow disease,” in the United States and Canada in 2003 and 2004, the use of beef liver as a source for bSOD was no longer possible and the manufacture of this product was discontinued. Accordingly, in 2004 we did not sell any bSOD and we do not expect future sales of bSOD. During 2003, we recorded bSOD sales of \$562,000.

*Securities regulation compliance in France and legal proceedings involving the AMF in France have resulted in, and may in the future result in, unexpected financial consequences to the Company.*

In 1997, the Company completed an offering of its common stock to European investors, and listed the resulting shares on the Nouveau Marché in France. As a result of such listing, the Company has been subject to French securities laws and the securities regulations of the Autorité des Marchés Financiers (the “AMF”), the French regulatory agency overseeing the Nouveau Marché. The cost of complying with such securities laws and regulations can be substantial. The AMF engaged in an investigation alleging that the Company failed to file financial and other disclosure information as required under French law from 1999 through 2002. As a result of the investigation, the Company incurred substantial defense costs and paid a fine of approximately \$62,000. As of December 31, 2004, the Company recorded approximately \$183,000 related to the defense and settlement of the investigation, including foreign legal expenses of \$121,000 and fines imposed by the AMF of \$62,000. In a related legal proceeding before French judicial authorities, the Company incurred additional legal expenses and paid an additional approximately \$11,600 in settlement of any obligation to pay fines. Although the Company is not as of the date of this Report on Form 10-KSB/A aware of any pending AMF allegations, in the event the AMF would make additional allegations against the Company or in the event that the Company would be required to answer additional charges in French legal proceedings, the Company may incur further substantial costs and fines. No assurances can be given that the Company would be able to settle any such matters with the AMF, or if it does settle these matters with the AMF, that it would be able to do so on terms favorable to the Company.

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*Our success will require that we establish a strong intellectual property position and that we can defend ourselves against intellectual property claims from others.*

Maintaining a strong patent position is important to our competitive advantage. We currently have approximately 85 patents either granted or applied for in 15 countries with expiration dates ranging from 2006 to 2024. Litigation on patent-related matters has been prevalent in our industry and we expect that this will continue. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and the extent of future protection is highly uncertain, so there can be no assurance that the patent rights we have or may obtain will be valuable. Others may have filed, or may in the future file, patent applications that are similar or identical to ours. To determine the priority of inventions, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office that could result in substantial costs in legal fees and could substantially affect the scope of our patent protection. We cannot assure investors that any such patent applications will not have priority over our patent applications. Further, we may choose to abandon certain issued United States and international patents that we deem to be of lesser importance to our strategic direction, in an effort to preserve our financial resources. Abandonment of patents could substantially affect the scope of our patent protection. In addition, we may in future periods incur substantial costs in litigation to defend against patent suits brought by third parties or if we initiate such suits.

In addition to patent protection, we also rely upon trade secret protection for our confidential and proprietary information. There can be no assurance, however, that such measures will provide adequate protection for our trade secrets or other proprietary information. In addition, there can be no assurance that trade secrets and other proprietary information will not be disclosed, that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to or disclose our trade secrets and other proprietary information. If we cannot obtain, maintain or enforce intellectual property rights, competitors can design and commercialize competing technologies.

We may face challenges from third parties regarding the validity of our patents and proprietary rights, or from third parties asserting that we are infringing their patents or proprietary rights, which could result in litigation that would be costly to defend and could deprive us of valuable rights.

Extensive litigation regarding patents and other intellectual property rights has been common in the biotechnology and pharmaceutical industries. The defense and prosecution of intellectual property suits, United States Patent and Trademark Office interference proceedings, and related legal and administrative proceedings in the United States and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time-consuming to pursue and their outcome is uncertain. Litigation may be necessary to:

- enforce patents that we own or license;
- protect trade secrets or know-how that we own or license; or
- determine the enforceability, scope and validity of the proprietary rights of others.

Our involvement in any litigation, interference or other administrative proceedings could cause us to incur substantial expense and could significantly divert the efforts of its technical and management personnel. An adverse determination may subject us to loss of our proprietary position or to significant liabilities, or require us to seek licenses that may not be available from third parties. An adverse determination in a judicial or administrative proceeding, or a failure to obtain necessary licenses, may restrict or prevent us from manufacturing and selling our products. Costs associated with these arrangements may be substantial and may include ongoing royalties. Furthermore, we may not be able to obtain the necessary licenses on satisfactory terms, if at all. These outcomes could materially harm our business, financial condition and results of operations.

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*We may be exposed to liability due to product defects.*

The risk of product liability claims is inherent in the testing, manufacturing, marketing and sale of our products. We may seek to acquire additional insurance for liability risks. We may not be able to obtain such insurance or general product liability insurance on acceptable terms or in sufficient amounts. A product liability claim or recall could have a serious adverse effect on our business, financial condition and results of operations.

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*Disclosure controls are no assurance that the objectives of the control system are met.*

Although we have an extensive operating history, resources are limited for the development and maintenance of our control environment. We have a limited number of personnel and therefore segregation of duties can be somewhat limited as to their scope and effectiveness. We believe, however, that we are in reasonable compliance with the best practices given the environment in which we operate. Although existing controls in place are deemed appropriate for the prevention, detection and minimization of fraud, theft, and errors, they may result in only limited assurances, at best, that the total objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, can be detected and/or prevented and as such this is a risk area for investors to consider.

### **Risks Related to Our Common Stock**

*Our common stock is traded on the OTCBB, our stock price is highly volatile, and you may not be able to sell your shares of our common stock at a price greater than or equal to the price you paid for such shares.*

Our shares of common stock are currently traded on the Over the Counter Bulletin Board (“OTCBB”). Stocks traded on the OTCBB generally have limited trading volume and exhibit a wide spread between the bid/ask quotation. The market price of our common stock is extremely volatile. To demonstrate the volatility of our stock price, during the twelve-month period ending on December 31, 2004, the volume of our common stock traded on any given day has ranged from 0 to 542,342 shares. Moreover, during that period, our common stock traded as low as \$0.32 per share and as high as \$0.90 per share, a 281.25% difference. This may impact an investor’s decision to buy or sell our common stock. As of May 16, 2005 there were approximately 5,500 holders of our common stock. Factors affecting our stock price include:

- our financial results;
- fluctuations in our operating results;
- announcements of technological innovations or new commercial health care products or therapeutic products by us or our competitors;
- government regulation;
- developments in patents or other intellectual property rights;
- developments in our relationships with customers and potential customers; and
- general market conditions.

Furthermore, volatility in the stock price of other companies has often led to securities class action litigation against those companies. Any such securities litigation against us could result in substantial costs and divert management’s attention and resources, which could seriously harm our business and financial condition.

In addition, the 12,264,158 outstanding shares of our common stock, and the 12,877,366 shares of our common stock that are issuable upon exercise of warrants we have issued to the selling shareholders, may be sold into the market pursuant to a prospectus. We cannot control when and in what quantities the selling shareholders

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will choose to sell shares of our common stock pursuant to such prospectus and such sales may cause the price of our common stock to decline.

*Our common stock may be subject to “penny stock” rules which may be detrimental to investors.*

Our common stock may be, or may become, subject to the regulations promulgated by the United States Securities and Exchange Commission (the “SEC”) for “penny stock”. Penny stock includes any non-NASDAQ equity security that has a market price of less than \$5.00 per share, subject to certain exceptions. The regulations require that prior to any non-exempt buy/sell transaction in a penny stock, a disclosure schedule set forth by the SEC relating to the penny stock market must be delivered to the purchaser of such penny stock. This disclosure must include the amount of commissions payable to both the broker-dealer and the registered representative and current price quotations for the common stock. The regulations also require that monthly statements be sent to holders of penny stock that disclose recent price information for the penny stock and information of the limited market for penny stocks. These requirements may adversely affect the market liquidity of our common stock.

*Sales of our common stock may require broker-dealers to make special suitability determinations regarding prospective purchasers.*

Our common stock may be, or may become, subject to Rule 15g-1 through 15g-9 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which imposes certain sales practice requirements on broker-dealers which sell our common stock to persons other than established customers and “accredited investors” (generally, individuals with a net worth in excess of \$1,000,000 or an annual income exceeding \$200,000 (or \$300,000 together with their spouses)). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser’s written consent to the transaction prior to the sale. Applicability of this rule would adversely affect the ability of broker-dealers to sell our common stock and purchasers of our common stock to sell their shares of such common stock. Accordingly, the market for our common stock may be limited and the value negatively impacted.

*We will incur expenses in connection with the registration of certain of our shares of common stock which may be significant in relation to our revenues.*

We are required to pay the fees and expenses incurred by us incident to the registration of certain of our shares of common stock under a registration statement. These expenses may be significant in relation to our revenues. We have also agreed to indemnify certain of the selling shareholders against losses, claims, damages and liabilities arising out of or relating to any misstatements or omissions in such registration statement or any related prospectuses, including liabilities under the Securities Act. In the event such a claim is made in the future, such losses, claims, damages and liabilities arising therefrom could be significant in relation to our revenues.

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**ITEM 7. FINANCIAL STATEMENTS**

Board of Directors  
OXIS International, Inc.  
Portland, OR

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We have audited the accompanying consolidated balance sheet of OXIS International, Inc., and subsidiaries as of December 31, 2004 and 2003 and the related consolidated statements of operations, shareholders' equity and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

As discussed in Note 18 to the financial statements, certain errors resulting in an understatement of patent amortization, net losses and accumulated deficits for the years ending December 31, 2004 and 2003 were discovered by the management of the Company during the current year. Accordingly, adjustments have been made to the financial statements to correct these errors.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of OXIS International, Inc., and subsidiaries as of December 31, 2004 and 2003 and the results of its operations, shareholders' equity and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Williams & Webster, P.S.  
Certified Public Accountants

Spokane, Washington  
February 18, 2005, except Note 18 which is dated May 24, 2005.

**OXIS INTERNATIONAL, INC. AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS**  
**(In thousands of dollars)**

	<b>December 31, 2004 Restated</b>	<b>December 31, 2003 Restated</b>
<b><u>ASSETS</u></b>		
Current assets:		
Cash and cash equivalents	\$ 4,687	\$ 372
Accounts receivable, net of allowance of \$7 and \$4, respectively	229	251
Private placement proceeds receivable	2,250	—
Inventories	246	295
Prepaid expenses and other current assets	128	139
	<hr/>	<hr/>
Total current assets	7,540	1,057
Property, plant and equipment, net	61	42
Technology for developed products, net	—	101
Patents and patents pending, net	875	655
Other assets	—	30
	<hr/>	<hr/>
Total assets	\$ 8,476	\$ 1,885

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

## OXIS INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS – Continued  
(In thousands of dollars)

	December 31, 2004	December 31, 2003
<b><u>LIABILITIES AND SHAREHOLDERS' EQUITY</u></b>		
Current liabilities:		
Note payable to shareholders	\$ 1,360	\$ 160
Accounts payable	491	609
Accrued liabilities	774	220
Accrued payroll	55	104
	<u>2,680</u>	<u>1,093</u>
Total current liabilities		
Commitments and contingencies	—	—
Shareholders' equity:		
Convertible preferred stock - \$0.01 par value; 15,000,000 shares authorized:		
Series B – 428,389 shares issued and outstanding (aggregate liquidation preference of \$1,000)	4	4
Series C – 96,230 shares issued and outstanding	1	1
Common stock - \$0.001 par value; 95,000,000 shares authorized; 28,807,040 and 26,427,910 shares issued and outstanding at December 31, 2004 and 2003, respectively, and 12,264,158 and 0 issuable at December 31, 2004 and 2003, respectively	41	26
Stock options	162	123
Warrants	4,161	236
Additional paid-in capital	64,114	60,365
Accumulated deficit	(62,270)	(59,572)
Accumulated other comprehensive loss	(417)	(391)
	<u>5,796</u>	<u>792</u>
Total shareholders' equity		
	<u>\$ 8,476</u>	<u>\$ 1,885</u>
Total liabilities and shareholder's equity		

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

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**OXIS INTERNATIONAL, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(In thousands of dollars, except earnings per share data)**

	Years Ended December 31,	
	2004 Restated	2003 Restated
Product revenues	\$ 1,914	\$ 2,740
License revenues	450	—
<b>Total revenue</b>	<b>2,364</b>	<b>2,740</b>
Cost of product revenues	1,216	1,496
<b>Gross profit</b>	<b>1,148</b>	<b>1,244</b>
Operating expenses:		
Research and development	278	409
Selling, general and administrative	1,843	1,648
Foreign legal proceedings	183	—
Restructuring charges	605	—
<b>Total operating expenses</b>	<b>2,909</b>	<b>2,057</b>
<b>Operating income (loss)</b>	<b>(1,761)</b>	<b>(813)</b>
Other income and expenses:		
Other income	19	8
Interest income	1	1
Financing fees	(856)	—
Interest expense	(101)	(14)
<b>Total other income and expenses</b>	<b>(937)</b>	<b>(5)</b>
<b>Loss before income taxes</b>	<b>(2,698)</b>	<b>(818)</b>
Income taxes	—	—
<b>Loss from continuing operations</b>	<b>(2,698)</b>	<b>(818)</b>
Loss from discontinued operations (net of taxes)	—	(13)
<b>Net loss</b>	<b>(2,698)</b>	<b>(831)</b>
Other comprehensive income/(loss)		
Foreign currency translation adjustment	(26)	54
<b>Comprehensive loss</b>	<b>\$ (2,724)</b>	<b>\$ (777)</b>
<b>Net loss per common share – basic and diluted</b>	<b>\$ (0.10)</b>	<b>\$ (0.04)</b>
<b>Weighted average number of shares used in computation – basic and diluted</b>	<b>26,828,289</b>	<b>18,205,164</b>

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

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**OXIS INTERNATIONAL, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY**  
**YEARS ENDED DECEMBER 31, 2004 AND 2003**

	Preferred Stock		Common Stock		Options & Warrants	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total shareholders' equity
	Shares	Amount	Shares	Amount					
Balances, January 1, 2003-Restated	2,024,619	\$ 20,000	10,005,604	\$10,000	\$ 2,009,000	\$58,327,000	\$(58,741,000)	\$ (445,000)	\$ 1,180,000
Shares issued in connection with 1997 IMS business combination			100,000						
Conversion of Series F preferred shares to common	(1,500,000)	(15,000)	15,000,000	15,000					
Issuance of new warrants					67,000	(67,000)			
Exercise of warrants			1,133,000	1,000	(258,000)	483,000			226,000
Options exercised			155,973			21,000			21,000
Options issued for accrued expenses and services					123,000				123,000
Expiration of warrants					(1,582,000)	1,582,000			
Shares issued for services			33,333			19,000			19,000
Net loss for year ended 12/31/03							(831,000)		(831,000)
Foreign currency translation adjustment								54,000	54,000
Other comprehensive loss									
<b>Balance, December 31, 2003-Restated</b>	<b>524,619</b>	<b>5,000</b>	<b>26,427,910</b>	<b>26,000</b>	<b>359,000</b>	<b>60,365,000</b>	<b>(59,572,000)</b>	<b>(391,000)</b>	<b>792,000</b>
Options exercised			791,532	1,000	(5,000)	141,000			137,000
Shares issued for services			66,666			46,000			46,000
Options issued for services					44,000				44,000
Warrants issued as incentive for bridge loan					159,000				159,000
Shares and warrants issued for conversion of bridge loan			1,520,932	2,000	202,000	1,018,000			1,222,000
Shares and warrants issuable for private placement			12,264,158	12,000	3,564,000	2,544,000			6,120,000
Net loss for year ended 12/31/04							(2,698,000)		(2,698,000)
Foreign currency translation adjustment								(26,000)	(26,000)
Other comprehensive loss									
<b>Balance, December 31, 2004-Restated</b>	<b>524,619</b>	<b>\$ 5,000</b>	<b>41,071,198</b>	<b>\$41,000</b>	<b>\$ 4,323,000</b>	<b>\$64,114,000</b>	<b>\$(62,270,000)</b>	<b>\$ (417,000)</b>	<b>\$ 5,796,000</b>

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

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**OXIS INTERNATIONAL, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands of dollars)

	Years Ended December 31,	
	2004 Restated	2003 Restated
<b>Cash flows from operating activities:</b>		
Net loss	\$(2,698)	\$ (831)
Adjustments to reconcile net loss to cash used for operating activities:		
Depreciation and amortization	173	217
Common stock and stock options issued for services	90	89
Common stock issued for accrued interest	38	—
Gain on sale of investment	—	(8)
Discontinued operations	—	13
Amortization of deferred financing costs	654	—
Common stock warrants issued for financing fees	202	—
Changes in assets and liabilities:		
Accounts receivable	22	(63)
Inventories	49	6
Other current assets	11	(1)
Accounts payable	(118)	288
Customer deposits	—	(13)
Accrued payroll, payroll taxes and other	505	104
Other assets	30	(30)
Net cash used by operating activities	(1,042)	(229)
<b>Cash flows from investing activities:</b>		
Proceeds from sale of investment	—	62
Purchases of equipment	(47)	(13)
Additions to other assets	(262)	(147)
Net cash provided by (used for) investing activities	(309)	(98)
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of stock with warrants attached, net of financing charges	3,870	—
Short-term borrowings with warrants attached net of deferred financing charges	486	—
Proceeds from short-term borrowings	1,200	—
Proceeds from exercise of warrants	—	226
Proceeds from exercise of stock options	136	21
Net cash provided by financing activities	5,692	247
Other comprehensive gain (loss)—foreign currency translation	(26)	28
Net increase (decrease) in cash and cash equivalents	4,315	(52)
Cash and cash equivalents—beginning of period	372	424
Cash and cash equivalents—end of period	\$ 4,687	\$ 372

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

**OXIS INTERNATIONAL, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS - Continued**  
**(In thousands of dollars)**

	For the Year Ended December 31,	
	2004	2003
Supplemental cash flow disclosures:		
Interest paid	\$ 28	\$ —
Income taxes paid	\$ —	\$ —
Non-cash investing and financing:		
Issuance of common stock for services	\$ 46	\$ 19
Issuance of warrants for financing fees	\$ 202	\$ —
Issuance of stock options for accrued expenses and services	\$ 44	\$ 123
Debt discount on convertible bridge loans	\$ 570	\$ —
Conversion of preferred stock into common stock	\$ —	\$ 15
Expiration of warrants	\$ —	\$ 1,582
Issuance of common stock for conversion of convertible bridge loans & accrued interest	\$ 609	\$ —
Discontinued operations	\$ —	\$ 13

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

**OXIS INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**YEARS ENDED DECEMBER 31, 2004 AND 2003**

**1. Description of Business and Basis of Presentation**

OXIS International, Inc. (“OXIS” or “the Company”) is a biopharmaceutical/nutraceutical company engaged in the development of research assays, diagnostics, nutraceutical and therapeutic products, which include new technologies applicable to conditions and/or diseases associated with oxidative stress. Oxidative stress is associated with an excess of free radicals, reactive oxygen species (“ROS”), and/or a decrease in antioxidant levels with a resultant development of tissue or organ damage. Oxidative stress can cause tissue injury by triggering cell death or inciting a tissue-damaging inflammatory response. The Company has invested significant resources to build an early and substantial patent position on both its antioxidant therapeutic technologies and selected oxidative stress assays.

Assays to measure markers of oxidative stress are manufactured by the Company in the United States and are sold directly to researchers and to distributors for resale to researchers, primarily in Europe, the United States and Japan. The Company previously sold pharmaceutical forms of superoxide dismutase (SOD) for human and research veterinary use but further sales of this product are not expected.

The Company is structured into two wholly owned subsidiaries, OXIS Health Products, Inc. and OXIS Therapeutics, Inc. The Company’s commercial health products business, which markets research and commercial diagnostic assays and fine chemicals to research and clinical laboratories and other customers, has been carried out by OXIS Health Products, Inc. The Company’s pharmaceutical and nutraceutical discovery and research business, which is focused on new drugs and compounds to treat diseases associated with tissue damage from free radicals and ROS, is being carried out by OXIS Therapeutics, Inc. As discussed in Note 12, Segment Reporting, the Company manages its business on the basis of one reportable segment: its health products and pharmaceutical products.

Consolidated within OXIS Health Products, Inc. is OXIS Instruments, Inc., incorporated in Pennsylvania. OXIS Instruments, Inc. closed in July 2001 at which time all employees of the instruments manufacturing facility were terminated. The final transactions of the business occurred in November 2003.

Consolidated within OXIS Therapeutics, Inc., incorporated in Delaware, is OXIS Acquisition Corporation, incorporated in Delaware; OXIS International, S.A., incorporated in France; OXIS Isle of Man Limited, incorporated in the Isle of Man and OXIS International (UK) Limited, incorporated in the United Kingdom. OXIS Acquisition Corporation holds the remaining assets of the Therox acquisition. OXIS International S.A. holds the remaining liability of the French acquisition. OXIS Isle of Man Limited holds the technology of the Bioxytech acquisition. OXIS International (UK) Limited was closed in July 2001, and discontinued business in December 2003. See Note 11.

Going Concern – At December 31, 2003, the Company’s auditors expressed a going concern qualification on the Company’s audited financial statements because of the Company’s negative working capital, history of recurring losses, and large accumulated deficit. The going concern qualification is not present with the Company’s audited financial statements at December 31, 2004 because of the Company’s positive working capital, large cash balance, and apparent ability to sustain itself for at least the next year.

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### 2. Significant Accounting Policies

This summary of significant accounting policies of OXIS International, Inc. is presented to assist in understanding the Company's financial statements. The financial statements and notes are representations of the Company's management, which is responsible for their integrity and objectivity. These accounting policies conform to accounting principles generally accepted in the United States of America, and have been consistently applied in the preparation of the financial statements.

*Principles of consolidation* – The accompanying financial statements include the accounts of the Company as well as its subsidiaries. The functional currency of the Company's French subsidiary is the Euro. The foreign subsidiaries' assets and liabilities are translated at the exchange rates at the end of the year, and their statements of operations are translated at the average exchange rates during each year. Gains and losses resulting from foreign currency translation are recorded as other comprehensive income or loss and accumulated as a separate component of shareholders' equity. All significant intercompany balances and transactions are eliminated in consolidation.

*Cash equivalents* – Cash equivalents consist of money market accounts with commercial banks.

*Accounting method* – The Company's financial statements are prepared using the accrual method of accounting.

*Inventories* – Inventories are stated at the lower of cost or market. Cost has been determined by using the first-in, first-out method. Inventories at December 31, 2004 and 2003 consisted of the following:

	2004	2003
Raw materials	\$121,000	\$101,000
Work in process	23,000	65,000
Finished goods	102,000	129,000
Total	<u>\$246,000</u>	<u>\$295,000</u>

*Property, plant and equipment* – Property, plant and equipment is stated at cost. Depreciation of equipment is computed using the straight-line method over estimated useful lives of three to ten years. Leasehold improvements are amortized over the shorter of five years or the remaining lease term. Depreciation expense for the years ended December 31, 2004 and 2003 was \$21,000 and \$33,000, respectively.

Property, plant and equipment at December 31, 2004 and 2003, consisted of the following:

	2004	2003
Furniture and office equipment	\$ 295,000	\$ 305,000
Laboratory and manufacturing equipment	655,000	636,000
Leasehold improvements	63,000	63,000
Property, plant and equipment, at cost	<u>1,013,000</u>	<u>1,004,000</u>
Accumulated depreciation and amortization	<u>(952,000)</u>	<u>(962,000)</u>
Property, plant and equipment, net	<u>\$ 61,000</u>	<u>\$ 42,000</u>

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Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144") establishes a single accounting model for long-lived assets to be disposed of by sale, including discontinued operations. SFAS No. 144 requires that these long-lived assets be measured at the lower of carrying amount or fair value less cost to sell, whether reported in continuing operations or discontinued operations. The Company does not believe any adjustments are needed to the carrying value of its assets at December 31, 2004.

*Research and development costs* – Research and development costs are charged to operations as incurred.

*Patents and technology for developed products* – The Company's accounting policies for patents are as follows: (a) acquired patents are recorded at acquisition cost and (b) internally developed patents – the following costs are capitalized (1) legal fees from the costs incurred in successful defense to the extent of an evident increase in the value of the patents (2) other patent fees (legal, registration), (3) models and drawings required for registration. Patents are being amortized on a straight-line basis over the shorter of the remaining life of the patent or ten years. All research and development costs incurred in developing the patentable idea are expensed as incurred. The Company begins to amortize the patent or patent pending in the quarter after the costs have been incurred. Patent pendings are amortized over twenty years or until the granted patent's life has been determined if shorter. Most of the Company's patented compounds are not marketed or sold until the patents have been approved.

The assets "Technology for developed products" were acquired in business combinations and were amortized over the estimated useful lives of seven to ten years. These assets, which had a historical cost of approximately \$1,530,000, were fully amortized as of December 31, 2004. Patents are amortized on a straight-line basis over the shorter of the remaining life of the patent or ten years. Amortization expense as of December 31, 2004 and 2003, is \$77,000 and \$82,000, respectively.

In accordance with SFAS No. 144, the Company periodically reviews net cash flows from sales of products and projections of net cash flows from sales of products on an undiscounted basis to assess recovery of recorded cost of intangible assets.

*Compensated absences* – Employees of the Company are entitled to paid vacation, paid sick days and personal days off, depending on job classification, length of service, and other factors. The Company accrues vacation expense throughout the year and records the expense in accrued payroll.

*Derivative instruments* – The Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 133, "Accounting for Derivative Instruments and Hedging Activities," as amended by SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities – Deferral of the Effective Date of FASB No. 133", SFAS No. 138, "Accounting for Certain Derivative Instruments and Certain Hedging Activities", and SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." These statements establish accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. They require that an entity recognize all derivatives as either assets or liabilities in the balance sheet and measure those instruments at fair value.

If certain conditions are met, a derivative may be specifically designated as a hedge, the objective of which is to match the timing of gain or loss recognition on the hedging derivative with the recognition of (i) the changes in the fair value of the hedged asset or liability that are attributable to the hedged risk or (ii) the earnings effect of the hedged forecasted transaction. For a derivative not designated as a hedging instrument, the gain or loss is recognized in income in the period of change.

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Historically, the Company has not entered into derivatives contracts to hedge existing risks or for speculative purposes.

At December 31, 2004 and 2003, the Company has not engaged in any transactions that would be considered derivative instruments or hedging activities.

*Stock-based compensation* – The Company accounts for stock issued for compensation in accordance with APB 25, “Accounting for Stock Issued to Employees.” Under this standard compensation cost is the difference between the exercise price of the option and fair market of the underlying stock on the grant date.

Statement of Financial Accounting Standards (“SFAS”) No. 123, “Accounting for Stock-Based Compensation” encourages the use of the fair value based method of accounting for stock-based employee compensation. Alternatively, SFAS No. 123 allows entities to continue to apply the intrinsic value method prescribed by Accounting Principles Board (“APB”) Opinion 25, “Accounting for Stock Issued to Employees”, and related interpretations and provide pro forma disclosures of net income (loss) and earnings (loss) per share, as if the fair value based method of accounting had been applied to employee awards. The Company follows the fair valued based method for non-employee awards and has elected to continue to apply the provisions of APB Opinion 25 and provide the disclosures required by SFAS No. 123 and SFAS No. 148, “Accounting for Stock-Based Compensation – Transition and Disclosure.” The following table illustrates the effect on net loss and loss per share if the fair value based method had been applied to all awards:

	Year Ended December 31,	
	2004	2003
Net loss:		
As reported	\$(2,698,000)	\$ (831,000)
Stock-based compensation determined under the fair value based method:		
Interim executive services	(47,000)	—
Employees	(277,000)	(490,000)
Pro forma	\$(3,022,000)	\$(1,321,000)
Net loss per share—basic and diluted:		
As reported	\$ (0.10)	\$ (0.04)
Pro forma	\$ (0.11)	\$ (0.07)

For the purpose of computing the pro forma expense, the fair value of each option is estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Grants issued in	
	2004	2003
Dividend yield	0%	0%
Expected volatility	73%	107%
Risk-free interest rate	4.25%	4.7%
Expected lives	10 Years	10 Years
Weighted average grant-date fair value of Options granted during the period (including non-employees)	\$ 0.46	\$ 0.35

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*Product sales* – The Company manufactures, or has manufactured on a contract basis, research and diagnostic assays and fine chemicals, which are its primary products sold to customers. Revenue from the sale of the Company's products, including shipping fees, if any, is recognized when title to the products is transferred to the customer (which usually occurs upon shipment or delivery, depending upon the terms of the sales order) and when collectibility is reasonably assured.

Revenue from sales to distributors of the Company's products is recognized, net of allowances, upon delivery of product to the distributors. According to the terms of individual distributor contracts, a distributor may return product up to a maximum amount and under certain conditions contained in the contract. Allowances are calculated based upon historical data, current economic conditions and the underlying contractual terms.

*Intellectual Property License Fees* – The Company recognizes license fee revenue for licenses to our intellectual property when earned under the terms of the agreements. Generally, revenue is recognized upon transfer of the license unless we have continuing obligations for which fair value cannot be established, in which case the revenue is recognized over the period of the obligation. The Company considers all arrangements with payment terms extending beyond twelve months not to be fixed or determinable. In certain licensing arrangements there is provision for a variable fee as well as a non-refundable minimum amount. In such arrangements, the amount of the non-refundable minimum guarantee is recognized upon transfer of the license and collectibility is reasonably assured unless we have continuing obligations for which fair value cannot be established and the amount of the variable fee in excess of the guaranteed minimum is recognized as revenue when it is fixed and determinable.

*Royalties* – We recognize royalty revenue based on reported sales by third party licensees of products containing our materials, software and intellectual property. Non-refundable royalties, for which there are no further performance obligations, are recognized when due under the terms of the agreements.

*Accounts receivable* – The Company carries its accounts receivable at cost less an allowance for doubtful accounts. 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 conditions.

The Company's policy allows the accrual of interest on trade receivables 30 days after due date. A receivable is considered past due if payments have not been received by the terms set by the Company. When all internal collection efforts have been exhausted, accounts are written off as uncollectible and turned over for collection. Interest is assessed at the discretion of the Company.

*Advertising and promotional fees* – Advertising expenses consist primarily of costs incurred in the design, development, and printing of Company literature and marketing materials. The Company expenses all advertising expenditures as incurred. The Company's advertising expenses were \$1,000 and \$14,000 for the years ended December 31, 2004 and 2003, respectively.

*Income taxes* – Deferred income taxes, reflecting the net tax effects of temporary differences between the carrying amount of assets and liabilities recognized for financial reporting purposes and the amounts recognized for income tax purposes, are based on tax laws currently enacted. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. See Note 10.

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*Net loss per share* - Net loss per share is computed based upon the weighted average number of common shares outstanding (“basic”) and, if dilutive, the incremental shares issuable upon the assumed exercise of stock options or warrants and the assumed conversion of preferred stock (“dilutive”). Due to the net losses in 2004 and 2003, the computation of dilutive net loss per share is antidilutive and therefore is the same as basic.

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Possible common stock dilutions include the following:

Preferred Stock Series B	85,678 shares
Preferred Stock Series C	27,800 shares
Warrants	15,927,833 shares
Qualified Stock Option	3,924,975 shares
Non-qualified Stock Option	747,888 shares

*Use of estimates* – The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities known to exist as of the date of the financial statements are published and the reported amounts of revenues and expenses during the reporting period. Uncertainties with respect to such estimates and assumptions are inherent in the preparation of the Company’s financial statements; accordingly, it is possible that the actual results could differ from these estimates and assumptions that could have a material effect on the reported amounts of the Company’s financial position and results of operations.

*Fair value of financial instruments* – The carrying amount reported in the balance sheet for cash and cash equivalents, accounts receivable, inventories, prepaid and other current assets, notes payable, customer deposits and accounts payable, accrued payroll and payroll taxes, and other accrued liabilities approximates fair value due to the short-term nature of the accounts.

*Reclassification* - Certain amounts from prior periods have been reclassified to conform to the current period presentation. This reclassification has resulted in no changes to the Company’s accumulated deficit or net losses presented.

*New Accounting Pronouncements* – In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 153. This statement addresses the measurement of exchanges of nonmonetary assets. The guidance in APB Opinion No. 29, “Accounting for Nonmonetary Transactions,” is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in that opinion; however, included certain exceptions to that principle. This statement amends Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. This statement is effective for financial statements for fiscal years beginning after June 15, 2005. Earlier application is permitted for nonmonetary asset exchanges incurred during fiscal years beginning after the date of this statement is issued. Management believes the adoption of this statement will have no impact on the financial statements of the Company.

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 152, which amends FASB statement No. 66, “Accounting for Sales of Real Estate,” to reference the financial accounting and reporting guidance for real estate time-sharing transactions that is provided in AICPA Statement of Position (SOP) 04-2, “Accounting for Real Estate Time-Sharing Transactions.” This statement also amends FASB Statement No. 67, “Accounting for Costs and Initial Rental Operations of Real Estate Projects,” to state that the guidance for (a) incidental operations and (b) costs incurred to sell real estate projects does not apply to real estate time-sharing transactions. The accounting for those operations and costs is subject to the guidance in SOP 04-2. This statement is effective for financial statements for fiscal years beginning after June 15, 2005. Management believes the adoption of this statement will have no impact on the financial statements of the Company.

In December 2004, the Financial Accounting Standards Board issued a revision to Statement of Financial Accounting Standards No. 123R, “Accounting for Stock Based Compensations.” This statement supercedes APB

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Opinion No. 25, "Accounting for Stock Issued to Employees," and its related implementation guidance. This statement establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. It also addresses transactions in which an entity incurs liabilities in exchange for goods or services that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity instruments. This statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. This statement does not change the accounting guidance for share based payment transactions with parties other than employees provided in Statement of Financial Accounting Standards No. 123. This statement does not address the accounting for employee share ownership plans, which are subject to AICPA Statement of Position 93-6, "Employers' Accounting for Employee Stock Ownership Plans." The Company has not yet determined the impact to its financial statements from the adoption of this statement.

In November 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 151, "Inventory Costs — an amendment of ARB No. 43, Chapter 4." This statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that ". . . under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so abnormal as to require treatment as current period charges. . . ." This statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Management does not believe the adoption of this statement will have any immediate material impact on the Company.

In May 2003, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" (hereinafter "SFAS No. 150"). SFAS No. 150 establishes standards for classifying and measuring certain financial instruments with characteristics of both liabilities and equity and requires that those instruments be classified as liabilities in statements of financial position. Previously, many of those instruments were classified as equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The Company's adoption of this statement did not have an impact on the financial statements of the Company.

In April 2003, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities" (hereinafter "SFAS No. 149"). SFAS No. 149 amends and clarifies the accounting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities". This statement is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The adoption of SFAS No. 149 did not have an impact on the financial statements of the Company.

### **3. Notes Payable to Shareholders**

Notes payable to shareholders at December 31, 2004 and 2003 included a \$160,000, 8% unsecured note which was originally due in May 1997 and is, therefore, delinquent. The note is currently due on demand.

Notes payable to shareholders at December 31, 2004 includes the Axonyx loan, described more fully in Note 5.

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**4. Convertible Bridge Loans**

On January 9, 2004, the Company received \$570,000 in loans and issued promissory notes, with terms of 12 months, convertible into 1,425,000 shares of the Company's common stock (or more in the event of a default by the Company). The Company also issued warrants to the lenders exercisable for up to 712,500 shares of common stock, plus additional shares for accrued interest, at an exercise price of \$0.50 per share. The Company recognized deferred financing fees totaling \$570,000 consisting of approximately \$411,000 related to the conversion feature of the notes and \$159,000 with related to the value of the warrants. These deferred financing fees, which were valued using the Black-Scholes pricing model, were amortized over the 12 month term of the notes.

The Company received notice on December 30, 2004, that all lenders had irrevocably converted their promissory notes and accrued interest into common stock. As a result, the Company issued 1,520,934 shares of common stock to the noteholders. As an incentive for the note holders to convert their notes to common stock, the Company issued 760,467 additional warrants. Each warrant entitles the holder to purchase one share of the Company's common stock for \$1.00 for a period of five years. These warrants were valued at approximately \$202,000 and have been included in financing fees for the year ended December 31, 2004. Upon conversion of the bridge loans, the Company expensed all remaining unamortized deferred financing fees related to the conversion feature and warrants issued with the bridge loans.

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### **5. Axonyx Loan**

On June 1, 2004, the Company secured a \$1,200,000 loan from its majority shareholder, Axonyx Inc. The note underlying the loan bears interest of 7% per annum, payable quarterly, matures on May 31, 2005, and is secured by the Company's intellectual property.

In the event that the Company completed an equity or convertible debt financing approved by Axonyx, which results in net proceeds to the Company of at least \$2,000,000, the Company's indebtedness to Axonyx would become immediately due and payable.

Due to the completed private placement in January 2005 of 12,264,158 shares of its common stock for \$6,500,000, the Company paid, to Axonyx, the full amount of the note, plus interest due, in cash on January 6, 2005. See Note 6.

### **6. Shareholders' Equity**

*Common Stock* – Each share of common stock is entitled to one vote at the Company's annual meeting of stockholders.

During the year ended December 31, 2004, a total of 791,532 shares of common stock were issued to employees and consultants upon the exercise of stock options at an average price of \$0.18 per shares. A total of 66,666 shares were issued to a consultant for services valued at \$47,000, or \$0.71 per share. A total of 1,520,932 shares were issuable at December 31, 2004 for the conversion of short-term bridge loans and accrued interest. In addition, a total of 12,264,158 shares were issuable at December 31, 2004 (subsequently issued during January 2005), at \$0.53 per share, for the private placement of equity on December 30, 2004. As of December 31, 2004, the Company had received, from a private placement of its stock, \$4,250,000 in cash and a receivable of \$2,250,000 that was subsequently collected in January 2005. In addition, within the conditions of the private placement, a total of 12,877,364 warrants were issued for common stock. Fifty percent of the warrants bear an exercise price of \$0.66 and the other fifty percent bear an exercise price of \$1.00.

*Preferred Stock* –The 428,389 outstanding shares of Series B preferred stock are convertible into and have voting rights equivalent to 85,678 shares of common stock. The Series B preferred stock has certain preferential rights with respect to liquidation and dividends. Holders of Series B preferred stock are entitled to noncumulative annual dividends at the rate of \$0.115 per share if and when declared by the Company's board of directors. No dividends to Series B preferred stockholders were issued or unpaid during 2004.

The 96,230 shares of Series C preferred stock are convertible into 27,800 shares of the Company's common stock at the option of the holders at any time. The conversion ratio is based on the average closing bid price of the common stock for the fifteen consecutive trading days ending on the date immediately preceding the date notice of conversion is given, but cannot be less than .20 or more than .2889 common shares for each Series C preferred share. The conversion ratio may be adjusted under certain circumstances such as stock splits or stock dividends. The Company has the right to automatically convert the Series C preferred stock into common stock if the average closing bid price of the Company's common stock on the Nasdaq National Market for 15 consecutive trading days exceeds \$13.00. Each share of Series C preferred stock is entitled to the number of votes equal to .26 divided by the average closing bid price of the Company's common stock during the fifteen consecutive trading days immediately prior to the date such shares of Series C preferred stock were purchased. In the event

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of liquidation, the holders of the Series C preferred stock shall participate on an equal basis with the holders of the common stock (as if the Series C preferred stock had converted into common stock) in any distribution of any of the assets or surplus funds of the Company. The holders of Series C preferred stock are entitled to noncumulative dividends after the payment of dividends on Series B preferred stock if and when declared by the Company's board of directors. No dividends to Series C preferred stockholders were issued or unpaid during 2004.

On March 7, 2002, the Company consummated the sale of all 1,500,000 shares of its Series F preferred stock to Meridian Financial Group L.L.P. ("Meridian") at a price of \$1 per share, paid in cash. Each share of Series F preferred stock was initially convertible into ten (10) shares of the Company's common stock. As part of the sale, the Company also issued a warrant granting Meridian the right to purchase up to 1.5 million shares of common stock at \$1.00 per share. In June 2003, Meridian converted its shares of Series F preferred stock into 15,000,000 shares of the Company's common stock and distributed such shares, and the 1,500,000 warrants, to its members/investors and to Triax Capital Management, Inc. as managing member.

*Stock Warrants* – During July 2003, the board of directors of the Company offered all holders of warrants a reduced exercise price for a limited period of time. The exercise price for these warrants was reduced to \$0.20 per share, and the maturity date for 598,449 warrants issued in 1998 was extended to August 11, 2003. The exercise price for these warrants was previously \$1.00 per share. All warrants issued prior to July 1998 had lapsed and were not affected by this board action. The decrease of exercise price did not result in any change to the outstanding value of the warrants. Pursuant to the offered reduced exercise price, a total of 1,133,000 warrants were exercised at an aggregate purchase price of \$226,600. As part of the offer, with each share of stock issued one new warrant was issued having a \$1.00 exercise price and a two-year life.

During January 2004, the Company issued warrants to purchase 712,500 common shares at an exercise price of \$0.50 in connection with the bridge loans. Each warrant bears a five-year life.

During December 2004, the Company issued warrants to purchase 760,469 common shares at an exercise price of \$1.00 in connection with the conversion of the bridge loans to common stock. Each warrant bears a five-year life.

Warrants to purchase 1,985,678 common shares at an exercise price of \$1.00 were issued in connection with the sale of common shares during 1998 expired in April and May 2003.

Warrants to purchase 1,454,449 common shares at an exercise prices of \$1.00 were issued in connection with the sale of common shares during 2000 expired in May 2003.

*Stock Options*—The Company has a stock incentive plan under which 4,250,000 shares of the Company's common stock are reserved for issuance (the "1994 Plan"). The 1994 Plan permits the Company to grant stock options to acquire shares of the Company's common stock, award stock bonuses of the Company's common stock, and grant stock appreciation rights. This Plan expired during 2003 and no further issuances will occur.

During the 2003 annual meeting of stockholders held in June 2003, the stockholders approved the adoption of the 2003 Stock Incentive Plan ("2003 Plan"), effective July 1, 2003. The 2003 Plan, under which 3,300,000 shares of the Company's common stock is reserved, permits the Company to grant stock options to acquire shares of the Company's common stock, award stock bonuses of the Company's common stock, and grant stock appreciation rights.

At December 31, 2004, options issued pursuant to the 1994 Plan to acquire 2,785,506 shares of common stock at exercise prices ranging from \$0.085 to \$15.30, and options issued pursuant to the 2003 Plan to acquire 1,139,469 shares of common stock at exercise prices ranging from \$0.45 to \$0.69 remained outstanding. Options

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issued outside the Plans are outstanding to acquire 747,888 shares of common stock at exercise prices of \$0.085 to \$8.438.

Options granted and outstanding under the plans as of December 31 are summarized as follows:

	2004		2003	
	Options	Weighted average exercise price	Options	Weighted average exercise price
Outstanding at beginning of year	3,707,911	\$ 0.89	2,834,041	\$ 1.28
Granted	1,120,000	0.54	1,520,469	.39
Exercised	741,532	(0.18)	(111,465)	(.14)
Forfeitures	161,404	(2.95)	(535,134)	(1.68)
Outstanding at end of year	3,924,975	\$ 0.84	3,707,911	\$ 0.89
Exercisable at end of year	3,444,531	\$ 0.88	3,328,686	\$ 0.94
Fair market value of options granted during the year	\$ 0.46		\$ 0.35	

The number of shares under option, weighted average exercise price and weighted average remaining contractual life of all options outstanding as of December 31, 2004, by range of exercise price were as follows:

Range of exercise price	Shares	Weighted average exercise price	Weighted average remaining life
\$ 0.08—\$ 0.88	3,444,425	\$ 0.39	8.36 years
\$ 1.38—\$ 1.91	242,750	\$ 1.88	5.12 years
\$ 2.50—\$ 4.53	107,000	\$ 3.22	3.24 years
\$ 5.78—\$ 8.45	115,800	\$ 8.00	1.39 years
\$11.41—\$15.30	15,000	\$ 13.74	.98 years

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The number of shares under option and weighted average exercise price of options exercisable as of December 31, 2004, by range of exercise price was as follows:

<u>Range of exercise price</u>	<u>Shares</u>	<u>Weighted average exercise price</u>
\$ 0.08—\$ 0.88	2,963,981	\$ 0.37
\$ 1.38—\$ 1.91	242,750	\$ 1.88
\$ 2.50—\$ 4.53	107,000	\$ 3.22
\$ 5.78—\$ 8.45	115,800	\$ 8.00
\$11.41—\$15.30	15,000	\$ 13.74

At December 31, 2004, the Company had the following additional stock options outstanding that were not issued pursuant to its stock incentive plans.

<u>Year Granted</u>	<u># Options</u>	<u>Exercise Price Range</u>	<u>Year of Expiration</u>
1996	7,000	\$ 8.44	2006
2000	25,000	\$ 1.38	2005
2001	78,438	\$ 0.085	2011
2002	57,730	\$0.12 to \$0.22	2007
2002	7,500	\$ 0.25	2005
2002	1,500	\$ 0.15	2012
2003	205,000	\$0.15 to \$0.31	2006
2003	300,000	\$ 0.14	2008
2003	46,000	\$0.15 to \$0.53	2013
2004	4,720	\$ 0.63	2007
2004	15,000	\$ 0.41	2014

## 7. Other Income

During the first quarter of 2003, the Company sold its equity interest in Caprius Inc., resulting in other income of \$8,000.

## **8. License Agreement**

On September 28, 2004, the Company and HaptoGuard Inc. (“HaptoGuard”) entered into a license agreement relating to the Company’s proprietary compound BXT 51072 and related compounds. Under the agreement, HaptoGuard has exclusive worldwide rights to develop, manufacture and market BXT-51072 and related compounds from the Company’s library of such antioxidant compounds. Further, HaptoGuard is responsible for worldwide product development programs with respect to licensed compounds. HaptoGuard has paid the Company an upfront license fee of \$450,000. The agreement provides that HaptoGuard must pay royalties to the Company, as well as additional fees for the achievement of development milestones in excess of \$21 million if all milestones are met and regulatory approvals are granted. The material milestones under the agreement which would generate future payments are as follows: upon initiation of Phase III clinical trials of the products; upon grant by the Food and Drug Administration (FDA) of marketing approval of the products; upon grant by the European Agency for the Evaluation of Medicinal Products (EMA) for marketing approval of the products; and upon grant of marketing approval of the products for each additional regulatory territory. The royalties paid by the licensee will begin upon the first commercial sale of the licensed products and will vary based upon formulations. However, there can be no assurances that royalty payments will result or that milestone payments will be realized. The Company has the right to terminate the agreement if the licensee fails to pay the Company any required payments under the agreement or if the licensee fails to comply with certain plan and timeline requirements relating to the development of the licensed compounds and such failure continues for 30 days after the Company has given notice to the licensee of such failure. Either party may terminate the agreement upon 30 days’ written notice upon certain events relating to the other party’s bankruptcy, insolvency, dissolution, winding up or assignment for the benefit of creditors, or upon the other party’s uncured breach of any material provision of the agreement. Otherwise, the agreement terminates when the Company’s underlying patents related to the licensed compounds expire.

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**9. Change of Control**

During the first quarter of 2004, Axonyx Inc. ("Axonyx") acquired approximately 52.3% of the issued and outstanding shares of the Company's common stock. Marvin S. Hausman, M.D., Axonyx chairman and chief executive officer, separately held approximately an additional 4.4% of the Company's issued and outstanding shares of common stock. Axonyx holdings were decreased to approximately 34% following a private placement of equity (completed in January 2005) consisting of 12,264,158 shares of the Company's common stock. Together with shares of the Company's common stock held by Dr. Hausman, the Axonyx affiliated group, at December 31, 2004, controlled approximately 37% of the Company's voting stock.

**10. Income Taxes**

*Deferred Taxes* - Deferred taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

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The tax effects of significant items comprising the Company's deferred taxes as of December 31 were as follows:

	<u>2004</u>	<u>2003</u>
<b>Deferred tax assets:</b>		
Federal net operating loss carryforward and capitalized research and development expenses	\$ 10,907,000	\$ 9,612,000
Federal R&D tax credit carryforward	457,000	491,000
State net operating loss carryforward and capitalized research and development expenses	1,246,000	1,127,000
Other	80,000	55,000
Deferred tax liabilities - book basis in excess of noncurrent assets acquired in purchase transactions	(142,000)	(142,000)
Deferred tax assets before valuation	12,548,000	11,143,000
Valuation allowance	(12,548,000)	(11,143,000)
<b>Net deferred tax assets</b>	<b>\$ —</b>	<b>\$ —</b>

The prospective tax benefits of the net operating losses of \$15,410,000 which existed at the date of acquisition (September 7, 1994) of the French subsidiary will be recorded as a reduction of income tax expense when and if realized. Due to the closure of the French subsidiary's operations in early 1999, it is unlikely that the Company will ever realize any benefit from the French subsidiary's operating loss carryforwards.

The prospective tax benefits of the net operating losses of \$1,032,000 which existed at the date of acquisition (December 31, 1997) of Innovative Medical Systems Corp. will be recorded as a reduction of the net unamortized balance of property, plant and equipment and intangible assets of \$465,000 when and if realized.

Statement of Financial Accounting Standards No. 109 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's history of operating losses, management has provided a valuation allowance equal to its net deferred tax assets.

*Tax Carryforwards* – At December 31, 2004, the Company had net operating loss carryforwards of approximately \$14,654,000 to reduce United States federal taxable income in future years, and research and development tax credit carryforwards of \$457,000 to reduce United States federal taxes in future years. These carryforwards expire as follows:

<u>Year of expiration</u>	<u>United States net operating loss carryforward</u>	<u>R&amp;D tax credit carryforward</u>
2005	\$ 25,000	\$ 46,000
2006	44,000	176,000
2007	4,000	18,000
2008	675,000	6,000
2009-2024	13,906,000	211,000
No expiration	—	—
	<u>\$ 14,654,000</u>	<u>\$ 457,000</u>

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During 2002, the Company issued preferred stock with voting rights, which would be regarded as a control change under the Internal Revenue Code (IRC). Under IRC Section 382, a control change will limit the utilization of the net operating losses. The Company has not determined the effects of any limitations on the value of net operating losses or any tax credits outstanding prior to the control change.

### **11. Discontinued Operations**

During December 2003, the Company made the decision to discontinue the operations of its United Kingdom subsidiary. As the result of this decision, there is a loss of \$13,000 for accumulated translation adjustments in 2003.

### **12. Segment Reporting**

The Company determines and discloses its segments in accordance with Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information" (hereinafter "SFAS No. 131") which uses a "management" approach for determining segments. The management approach designates the internal organization that is used by management for making operating decisions and assessing performance as the source of the Company's reportable segments. SFAS No. 131 also requires disclosures about products or services, geographic areas, and major customers. The Company's management reporting structure provided for two segments in prior years and the first quarter of 2004 and accordingly, separate segment information was presented.

The Company currently manages its business on the basis of one reportable segment: its health and pharmaceutical products. The Company's executives use consolidated results of the Company's operations to make decisions affecting the development, manufacturing, and marketing of this business.

While the Company has historically been organized into two reportable segments (health products and therapeutic development), the Company manages its operations in one segment in order to better monitor and manage its basic business: the development and sale of research diagnostics, nutraceutical and therapeutic products.

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Revenue attributed to North America includes shipments to customers in the United States, Canada and Mexico. Revenue from Europe, Middle East and Africa (EMEA), Latin America and Asia Pacific includes shipments to customers in each region. Information relating to revenue from external customers from different geographical areas is as follows:

<u>(In Thousands)</u>	<u>Year Ended December 31,</u>	
	<u>2004</u>	<u>2003</u>
North America	\$ 1,142	\$ 1,242
EMEA	427	1,046
Latin America	10	2
Asia Pacific	335	450
Total	\$ 1,914	\$ 2,740

Revenue from Japan totaled \$221,000 and \$333,000 for fiscal years ended December 31, 2004 and 2003, respectively. Revenues from Spain totaled \$596,000 for the fiscal year ended December 31, 2003. No other countries outside of the United States exceeded 10% of the Company's consolidated total revenue in any year presented. No Country outside of the United States holds any of the Company's consolidated long-lived assets.

### **13. Concentrations**

*Bank Accounts* – The Company maintains cash in money market accounts. The funds on deposit are not insured by the FDIC, and therefore, approximately \$4,687,000 is at risk on December 31, 2004.

*Customers* – In 2004, approximately 40% of the Company's sales were attributable to six customers. In 2004, approximately 11% of the Company's total sales were from EMD Biosciences, Inc., a distributor customer located outside of the United States.

### **14. Commitments and Contingencies**

The Company leases its facilities in Oregon under an operating lease that expires in November 2005. Minimum lease payments to which the Company is committed is \$122,000 in 2005. Rental and occupancy expenses included in the accompanying statements of operations were \$134,000 in 2004 and \$152,000 in 2003.

In 1995, the Company consummated the acquisition of Therox Pharmaceuticals, Inc. ("Therox") wherein Therox was merged with and into a wholly owned subsidiary of the Company. In addition to the issuance of its common stock to Therox shareholders, the Company agreed to make payments of up to \$2,000,000 to the Therox stockholders based on the successful commercialization of Therox technologies. As of December 31, 2004, no additional payments have been made. The Company has not recorded a liability associated with this agreement because the Company does not believe that it has successfully commercialized any of the Therox technologies acquired.

In 1997, the Company acquired all of the outstanding common stock of Innovative Medical Systems Corp. ("IMS") in exchange for 200,000 shares of the Company's common stock issued immediately and additional shares to be issued. The name of IMS was changed to OXIS Instruments, Inc. during 1998. Additional common shares were to be issued to former IMS shareholders annually through 2003 depending on, among other things, future annual revenues of OXIS Instruments Inc. through 2002 and on the market price of the Company's common stock. During 2003, the Company issued 100,000 shares (the minimum number of shares

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required under the original agreement) to the former IMS shareholders. The Company does not believe that additional shares are or will be required to be issued to these shareholders.

*French filing obligations* – In 1997, the Company completed an offering of its common stock to European investors, and listed the resulting shares on the Nouveau Marché in France. The Company was notified that a Paris lower court (Tribunal de grande instance de Paris) on November 12, 2003, issued an order (the “Order”) requiring the Company (i) to file its 2002 Document de Reference (“2002 Reference Document”) as required under French law and the regulations of the Autorité des Marchés Financiers (the “AMF”), the French regulatory agency overseeing the Nouveau Marché, within eight days of the court’s Order (“filing deadline”) and (ii) if the Company has not filed with the AMF its 2002 Reference Document by the filing deadline, to pay a fine of 1,500 Euros for each day until it files its 2002 Reference Document with the AMF. Following the issuance of the Order, the Company (1) filed its 2002 Reference Document with the AMF and received written confirmation that its 2002 Reference Document has been registered and (2) appealed the Order to the extent that it imposed fines on the Company. The Company has since dismissed its appeal of the Order, and during the first quarter of 2004 paid approximately \$11,600 in settlement of any obligation to pay fines under the Order.

The AMF also engaged in a separate investigation relating to the Company’s failing to file financial and other disclosure information as required under French law from 1999 through 2002 (the “Investigation”). At a hearing before the Disciplinary Commission of the AMF on June 17, 2004 the Disciplinary Commission considered a report of the AMF investigator recommending that the Disciplinary Commission impose a fine of not less than 100,000 Euro. Following the hearing, the Disciplinary Commission ordered the Company to pay a fine of 50,000 Euro (approximately \$62,000) with respect to the Company’s failure to file financial and other disclosure information as required under French law from 1999 through 2002. The Company did not appeal this order and the fine has been paid. As of December 31, 2004, the Company has recorded approximately \$183,000 related to the defense and settlement of this investigation, including foreign legal expenses of \$121,000 and fines imposed by the AMF of \$62,000. These charges are recorded as a separate line item under Operating Expenses.

The Company and its subsidiaries are also parties to various other claims in the ordinary course of business. The Company does not believe that there will be any material impact on the Company’s financial position, results of operations or cash flows as a result of these claims.

### **15. Restructuring Charges**

Restructuring charges related to the Axonyx change of control include legal (\$196,000), management consulting (\$34,000), travel (\$8,000), executive search (\$22,000) and severance expenses (\$345,000).

### **16. Revenue Concentrations**

As discussed in Note 8, the Company signed an exclusive license agreement during the third quarter of 2004, resulting in revenues of \$450,000, or 19% of total revenues for 2004. There can be no assurances that future milestone events and payments will be realized or that the Company may be able to enter into additional future license agreements.

### **17. Subsequent Events**

*Axonyx loan* – Under the terms of a promissory note, the Company agreed to pay Axonyx \$1.2 million plus accrued interest upon the receipt by the Company of at least \$2,000,000 in net proceeds from a debt or equity offering. The equity funding of the private placement on December 30, 2004 is a triggering event requiring repayment of the indebtedness represented by the note. On January 6, 2005, after the closing of the transaction, the Company repaid the indebtedness represented by the note in full by paying to Axonyx \$1,222,380.

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*Other matters* - In January 2003, the Company negotiated the settlement of a \$19,000 accounts payable debt by offering to the other party a total of 94,961 shares of the Company's common stock per share. Although orally accepting this arrangement, the other party has failed to execute the related paperwork to complete the agreement. While the Company does expect to satisfy its obligation of \$19,000, there can be no assurances that the other party will accept stock in payment of the debt.

### **18. Correction of Error**

During 2005, the Company's management decided to correct the Company's accounting policy for patents and patents pending. The Company had not previously amortized its patents pending and only began amortizing once the patent was issued. In concurrence with a regulatory review, the Company has decided to begin amortizing patent costs in the quarter after they are incurred. The amortization expense will be treated as a cost of sales for all products currently being sold and as a research expense for patents awaiting final approval.

Accordingly the Company recognized amortization expense prior to January 1, 2003 of \$38,340 as a correction to prior accumulated deficits. The additional amortization expense for the years ending December 31, 2004 and 2003 were \$41,312 and \$39,970, respectively. These changes cause no material changes in losses per share. As of December 31, 2004, the cumulative increase to accumulated deficit was \$119,622.

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**ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

None.

**ITEM 8A. CONTROLS AND PROCEDURES**

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our Chief Executive officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information required to be included in this report. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

There has been no change in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

**ITEM 8B. OTHER INFORMATION**

None.

**PART III**

**ITEM 9. DIRECTORS, EXECUTIVE OFFICERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT**

The information required by this item is incorporated herein by reference to the material contained under the caption "Proposal No. 1-Election of Directors" in the Company's definitive proxy statement for the 2005 Annual Meeting of Shareholders.

**ITEM 10. EXECUTIVE COMPENSATION**

The information required under this item is incorporated herein by reference to the material contained under the caption "Compensation of Executive Officers" in the Company's definitive proxy statement for the 2005 Annual Meeting of Shareholders.

**ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The information required under this item is incorporated herein by reference to the material contained under the caption "Proposal No. 1-Election of Directors" in the Company's definitive proxy statement for the 2005 Annual Meeting of Shareholders.

**ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The information required under this item is incorporated herein by reference to the material contained under the caption "Proposal No. 1-Election of Directors" in the Company's definitive proxy statement for the 2005 Annual Meeting of Shareholders.

**ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K**

- (a) Exhibits specified by item 601 of Regulation S-B.  
See Exhibit Index - page 64.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

*Audit Fees* – The Company incurred aggregate fees and expenses of \$59,000 and \$44,000, respectively, from Williams & Webster, P.S. for the fiscal years 2004 and 2003 annual audit and for review of the Company's consolidated financial statements included in its Forms 10-QSB for the 2004 and 2003 fiscal years.

*Audit Related Fees* – None.

*Tax Fees* – The Company incurred aggregate fee and expenses of \$5,000 and \$5,000, respectively, from Williams & Webster, P.S. for the fiscal years 2004 and 2003 for professional services rendered for tax compliance, tax advice and tax planning.

*All Other Fees* – None.

The Company intends to continue using Williams & Webster, P.S. solely for audit and audit-related services, tax consultation and tax compliance services, and, as needed, for due diligence in connection with potential acquisitions, if any.



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**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Footnote</u>
2(a)	Share Exchange Agreement by and among Innovative Medical Systems Corp., OXIS International, Inc. and each of the shareholders who are signatories thereto	(1)
3(a)	Restated Certificate of Incorporation as filed in Delaware September 10, 1996 and as thereafter amended through March 1, 2002	(2)
3(b)	Bylaws of the Company as restated effective September 7, 1994 and as amended through April 29, 2003	(3)
4(a)	Forms of Common Stock and Warrant Purchase Agreement, Warrant to Purchase Common Stock, and Registration Rights Agreement Regarding Private Placement March-April, 2000	(4)
10(a)	OXIS International, Inc. Series B Preferred Stock Purchase Agreement dated July 18, 1995	(5)
10(b)	Series C Preferred Stock Subscription and Purchase Agreement (form); dated April 1996 (1,774,080 shares in total)	(6)
10(c)	Form of Promissory Notes dated March 27, 1997 - April 24, 1997	(7)
10(d)	Subscription Agreement, Warrant to Purchase Common Stock and Form of Subscription dated July 2003 – August 2003	(10)
10(e)	Executive Separation and Employment Agreement dated April 3, 2000, between the Company and Ray R. Rogers	(8)
10(f)	Addendum to Executive Separation and Employment Agreement between OXIS International, Inc. and Ray R. Rogers dated August 1, 2001	(9)
10(g)	Employment Agreement between OXIS International, Inc. and Ray R. Rogers dated June 1, 2003	(10)
10(h)	Employment Agreement between OXIS International, Inc. and Sharon Ellis dated June 1, 2003	(10)
10(i)	Note and Warrant Purchase Agreement, Form of Convertible Promissory Note and Form of Warrant to Purchase Common Stock dated January 9, 2004	(10)
10(j)	Form of Loan Agreement, Promissory Note and Security Agreement between OXIS International, Inc. and Axonyx, Inc. dated June 1, 2004	(11)
10(k)	Separation, Retirement and Consulting Agreement between Oxis International, Inc. and Ray R. Rogers, dated June 21, 2004	(12)
10(l)	Separation Agreement between OXIS International, Inc. and Sharon Ellis, dated July 13, 2004	(12)
10(m)	License Agreement between OXIS International, Inc. and Haptoguard, dated September 29, 2004**	(13)
10(n)	Securities Purchase Agreement, Registration Rights Agreement and Form of Common Stock Warrant, dated December 30, 2004	(14)
10(o)	Consulting Agreement between OXIS International, Inc. and Manus O'Donnell, dated October 14, 2004	(15)
10(p)	Form of Indemnification Agreement between OXIS International, Inc. and its Officers and Directors	(15)
10(q)	Ninth Amendment to Lease between OXIS International, Inc. and Rosan, Inc. dated November 11, 2004	(15)
21(a)	Subsidiaries of OXIS International, Inc.	(16)
31(a)	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	*
31(b)	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	*
32(a)	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	*
32(b)	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	*

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(1) Incorporated by reference to the Company's Form 8-K Current Report, dated January 15, 1998.

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- (2) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2002.
- (3) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003.
- (4) Incorporated by reference to the Company's Form 8-K Current Report dated March 3, 2000.
- (5) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1995.
- (6) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2002.
- (7) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1997.
- (8) Incorporated by reference to the Company's Form S-3 Registration Statement No. 333-40970 filed July 7, 2000 and effective December 22, 2000.
- (9) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.
- (10) Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2003.
- (11) Incorporated by reference to the Company's Form 8-K Current Report dated June 9, 2004.
- (12) Incorporated by reference to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2004.
- (13) Incorporated by reference to the Company's Quarterly Report on Form 10-QSB for the quarter ended September 30, 2004.
- (14) Incorporated by reference to the Company's Form 8-K/A Current Report dated February 8, 2004.
- (15) Incorporated by reference to the Company's Form SB-2 Registration Statement dated February 25, 2005.
- (16) Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2004.

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\* Filed with this Report.

\*\* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission pursuant to an application for confidential treatment.

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

I, Steven T. Guillen, certify that:

1. I have reviewed this report on Form 10-KSB/A of OXIS International, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;
4. The small business issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the small business issuer and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to

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materially affect, the small business issuer's internal control over financial reporting; and

5. The small business issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: June 15, 2005

/s/ STEVEN T. GUILLEN

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Steven T. Guillen  
Chief Executive Officer

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

I, Marvin S. Hausman, certify that:

1. I have reviewed this report on Form 10-KSB/A of OXIS International, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;
4. The small business issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the small business issuer and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to

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materially affect, the small business issuer's internal control over financial reporting; and

5. The small business issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: June 15, 2005

/s/ MARVIN S. HAUSMAN

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Marvin S. Hausman  
Principal Financial Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of OXIS International, Inc. (the "Company") on Form 10-KSB/A for the period ending December 31, 2004 as filed with the Securities and Exchange Commission on the date therein specified (the "Report"), I, Steven. T. Guillen, Chief Executive Officer of the Company, certify pursuant to 18 U.S.C. Section 1350 that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company at the dates and for the periods indicated.

This Certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission.

/s/ STEVEN T. GUILLEN

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Steven T. Guillen  
Chief Executive Officer  
June 15, 2005

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of OXIS International, Inc. (the "Company") on Form 10-KSB/A for the period ending December 31, 2004 as filed with the Securities and Exchange Commission on the date therein specified (the "Report"), I, Marvin S. Hausman, Acting Chief Financial Officer of the Company, certify pursuant to 18 U.S.C. Section 1350 that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company at the dates and for the periods indicated.

This Certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission.

/s/ MARVIN S. HAUSMAN

\_\_\_\_\_  
Marvin S. Hausman

Principal Financial Officer

June 15, 2005