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2004 Annual Report

Notice of Annual Meeting and Proxy Statement

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Dear Shareholders,

2004 marked a year of substantial change for Axonyx. As CEO, I am proud to lead this unique company during a significant and exciting point in its development. It is also a time of important scientific discovery and advances within the healthcare sector and specifically within the area of Axonyx's focus, Central Nervous System (CNS) diseases. Our ongoing efforts in this devastating disease area are driven by a call to action to provide the healthcare community with safe and effective treatments beyond the options available today.

Since Axonyx' inception in 1997, we have remained dedicated to becoming the leading company in the area of CNS diseases and in particular Alzheimer's disease. Alzheimer's disease (AD) afflicts more than 12 million people worldwide and is associated with national spending on patient care of \$100 billion annually, making it one of the most pressing medical, social and financial challenges facing the world today. We have committed the entire organization to serving this growing unmet medical need through a strategic resolve to maximize the long-term value of our drug pipeline, while minimizing unnecessary risks to our balance sheet, infrastructure and shareholders. We have adhered to this governing principle in responding to the challenges of drug development and making sound business decisions over the past year. As a result, we have made considerable strides in each of our core areas of focus, including our developmental pipeline, growth strategy, operational network and balance sheet.

2004: A Year of Decisions

In many ways, Axonyx operates as a very different company compared to just one year ago. With three lead compounds in development, we have placed sizeable emphasis on ensuring that our time and resources are tightly focused on making progress in the areas that present the greatest opportunity. For Axonyx, this means delivering on the drug development milestones within the timeframe we set forth.

We advanced Phenserine, an acetylcholinesterase inhibitor, into Phase III clinical trials in the anticipated timeframe. Despite the unforeseen results from our first Phase III clinical trial, which did not show statistically significant improvements over placebo for the protocol's primary memory and cognition endpoints, we remain encouraged by its safety profile that remained within an optimal range of marketability, as well as its unique dual mechanism of action. This is particularly important having recently announced interim statistical results from our Phase IIb beta-amyloid trial, which indicated the compound's potential to slow the progression of AD by reducing beta-amyloid levels. In its toxic form, beta-amyloid is thought to be a major causative factor in the development and progression of AD. A key priority for Axonyx is to show that Phenserine has the potential ability to combat this nerve cell degenerative effect. We expect to complete our Phase IIb trial evaluating this effect in the next nine to twelve months.

The decisions we made regarding the Phenserine program were based on a careful, thorough analysis of benefits and risks. We believe these decisions, given Phenserine Phase III trial results, were ones that make the most sense for our pipeline and business. Specifically, following the release of the trial results, Axonyx immediately took action to halt additional patient recruitment in our two ongoing Phase III trials. These were initiated in June and September 2004 and were designed to study the efficacy and safety of the immediate release formulation of Phenserine. We stand to benefit from this decision, as the information we receive following completion of the Phase IIb trial may provide additional data supporting the compound's efficacy and disease modifying potential, while affording substantial savings in Phase III development costs through 2005. A second critical decision involved the Phenserine reformulation program designed to optimize Phenserine's safety, efficacy and potential disease modifying profile, without requiring significant near-term investment. Results from the reformulation program should also be available in nine to twelve months. This convergence of events will play an integral role in ensuring that we are armed with the most comprehensive data available for determining next steps for the Phenserine program.

We also made progress in advancing Axonyx's other two lead compounds in development for the treatment of AD, Posiphen™ and Bisnorcymserine (BNC). Posiphen™, the positive isomer of Phenserine, has been shown in pre-clinical studies to decrease the formation of beta-amyloid and therefore has the potential to slow the progression of AD. The drug is in full pre-Investigational New Drug (IND) development, and we are working toward having a Phase I safety study completed by the end of 2005. BNC, a butyrylcholinesterase inhibitor for the potential treatment of the symptoms of memory and cognition loss in severe AD, is our third compound in development and

its profile is attractive as a potent lead from this drug class. It has a dual mechanism of action that may also inhibit the production of beta-amyloid, thus slowing disease progression. Given its early stage development, we are working toward an optimal scenario of submitting an IND for BNC by the fourth quarter of 2005, and also initiating a Phase I clinical trial in early 2006.

Underpinning our business development strategy is an aggressive focus on leveraging in- and out-licensing opportunities to maximize our potential for advancement and growth, resulting in financial upside for Axonyx and our shareholders. As is evident with Phenserine, our objectives surrounding the future of each of our compounds are to build the most attractive data and marketing package possible for partnership opportunities. We also remain committed to the discovery and acquisition of new compounds that demonstrate promise and the potential for significant return on our investment.

Throughout the year, we have continued to invest time and effort to create an expansive network of dedicated professionals from what was once thought of as a "virtual" company. While on paper, Axonyx is a five-employee company, we are proud to claim a proven, established network of employees, service providers, prominent opinion leaders and scientists in the CNS field, key members of academia, and an entire drug development management team. Through these relationships, we are able to remain abreast of prime opportunities within the CNS arena, as well as gain positive recognition that serves as a catalyst for other R&D companies to seek out Axonyx. More importantly, this streamlined structure continues to yield financial and operational benefits by helping to curb G&A expenses, provide operational flexibility and access to the influencers in the field, all the while allowing us to continue to meet our developmental milestones on time.

Perhaps our greatest achievement in the last year was the ability to strengthen our capital position. Through private placements and warrant exercises, the Company raised \$78 million in 2004. In the past two years, we have raised \$110 million, and as of the end of 2004 we have approximately \$90 million in cash and cash equivalents. A strong balance sheet provides us with the necessary flexibility to continue to pursue different strategic options as they relate to our drug development pipeline, and we are committed to a fiscally conservative approach to operating our business.

Looking Ahead

Our accomplishments in 2004 have set us on the right track to capitalize on market opportunities and deliver future growth. Our focus in 2005 will be on advancing the core pipeline, seeking ways to achieve long-term growth and maximizing the benefit and minimizing risk across all aspects of our business. There is no doubt that the rapidly rising unmet need in AD and other CNS disorders is a tremendous opportunity and validates our core mission. Having been faced with several difficult decisions over the past year, we emerge a stronger, more focused organization armed with the right people and strategy to help ensure continued growth and bring additional value to our pipeline, shareholders and millions of patients who inspire our dedication.

We appreciate your continued support.

Sincerely,



Gosse B. Bruinsma, M.D.
President & Chief Executive Officer
Axonyx Inc.

April 2005



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AXONYX INC.

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS

TO OUR STOCKHOLDERS:

The annual meeting of stockholders of Axonyx Inc. will be held at the offices of Eisner LLP, 750 Third Avenue, 16th Floor, New York, New York, 10017 on June 16, 2005, at 10:00 a.m. Eastern Daylight Time, for the following purposes:

1. To elect six directors by the holders of our common stock;
2. To ratify the appointment of Eisner LLP as our independent auditors for the fiscal year ending December 31, 2005; and
3. To transact such other business as may properly be brought before the meeting or any adjournment thereof.

The meeting may be adjourned from time to time and at any reconvened meeting action with respect to the matters specified in this notice may be taken without further notice to stockholders except as may be required by our by-laws. Stockholders of record at the close of business on April 29, 2005 are entitled to notice of, and to vote on, all matters at the meeting and any reconvened meeting following any adjournments thereof.

Whether or not you expect to be present, please sign, date and return the enclosed proxy sheet in the enclosed pre-addressed envelope as soon as possible. No postage is required if the enclosed envelope is used and mailed in the United States.

By Order of the Board of Directors



Marvin S. Hausman, M.D.
Chairman of the Board

May 16, 2005

PLEASE FILL IN, DATE AND SIGN THE ENCLOSED PROXY AND RETURN IT IN THE ENVELOPE PROVIDED AS PROMPTLY AS POSSIBLE, WHETHER OR NOT YOU PLAN TO ATTEND THE ANNUAL MEETING. IF YOU LATER DESIRE TO REVOKE YOUR PROXY FOR ANY REASON, YOU MAY DO SO IN THE MANNER DESCRIBED IN THE ATTACHED PROXY STATEMENT.

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**PROXY STATEMENT FOR ANNUAL MEETING
TO BE HELD JUNE 16, 2005**

GENERAL INFORMATION

The accompanying proxy is solicited by the Board of Directors of Axonyx Inc. (the "Board" or "Board of Directors") with its principal executive offices at 500 Seventh Avenue, 10th Floor, New York, New York 10018 ("Axonyx" or the "Company") to be voted at the 2005 Annual Meeting of Stockholders (the "Annual Meeting") to be held on June 16, 2005 at the offices of Eisner LLP, 750 Third Avenue, 16th Floor, New York, NY 10017 at 10:00 a.m. Eastern Daylight Time, and any adjournment thereof. When a proxy is properly executed and returned to Axonyx in time for the Annual Meeting, the shares it represents will be voted by the proxy holders in accordance with the instructions given in the proxy. If no direction is given in the proxy, the votes represented thereby will be voted in accordance with the recommendation of the Board of Directors with respect to each matter submitted to the Company's stockholders for approval. With respect to any other item of business that may come before the Annual Meeting, the proxy holders will vote in accordance with their best judgment. This Proxy Statement and the accompanying proxy are being sent to stockholders on or about May 16, 2005.

PROXY REVOCATION PROCEDURE

A proxy may be revoked at any time before it has been exercised (i) by written notice of revocation given to the Secretary of the Company, (ii) by executing and delivering to the Secretary a proxy dated as of a later date than a previously executed and delivered proxy (provided, however, that such action must be taken in sufficient time to permit the necessary examination and tabulation of the subsequent proxy before the vote is taken), or (iii) by attending the Annual Meeting and voting in person. Attendance at the Annual Meeting will not in and of itself revoke a proxy.

ABSTENTIONS, BROKER NON-VOTES

The presence, in person or by proxy, of the holders of a majority of the outstanding shares of Common Stock entitled to vote at the Meeting is necessary to constitute a quorum. Votes withheld from any nominee for election as a director, abstentions and broker "non-votes" are counted as present for purposes of determining the presence or absence of a quorum for the transaction of business. A "non-vote" occurs when a nominee holding shares for a beneficial owner votes on one proposal, but does not vote on another proposal because, in respect of such other proposal, the nominee does not have discretionary voting power and has not received instructions from the beneficial owner.

The election of directors by the stockholders shall be determined by a plurality of the votes cast by stockholders entitled to vote at the Meeting, and votes withheld will not be counted toward the achievement of a plurality. For ratification of the appointment of the Company's independent auditors, the affirmative vote of a majority of the shares present in person or represented by proxy at the Meeting and entitled to vote on such matter is required for approval. The vote on each proposal submitted to stockholders is tabulated separately. Abstentions are included in the number of shares present and voting on each proposal. Broker non-votes are not considered for the particular proposal and have the practical effect of reducing the number of affirmative votes required to achieve a majority for such proposal by reducing the total number of votes from which the majority is calculated.

HOLDERS OF RECORD, QUORUM

Holders of record of our shares of common stock, par value \$0.001 per share ("Common Stock"), our only class of issued and outstanding voting securities, at the close of business on April 29, 2005 (the "Record Date") are entitled to vote at the Annual Meeting. There were 53,665,518 shares of Common Stock outstanding as of the Record Date. The presence, in person or by proxy, of the holders of a majority of the outstanding shares of Common Stock entitled to vote at the Meeting is necessary to constitute a quorum for the transaction of business at the Meeting. Stockholders are entitled to cast one vote per share on each matter presented for consideration by the stockholders. A list of stockholders entitled to vote at the Annual Meeting will be available for examination by any stockholder for a proper purpose during normal business hours at the executive offices of the Company for a period of at least 10 days preceding the Annual Meeting.

PROPOSAL 1 ELECTION OF DIRECTORS

The Board of Directors

The Company's business is managed under the direction of its Board of Directors. The Board of Directors has designated as nominees for re-election six of the seven directors currently serving on the Board. Gerard J. Vlak, a current director, has declined to stand for re-election at the meeting. See "Nominees for Director" below for profiles of the nominees. After the election of the directors at the meeting, the Company's Board will have six directors.

The Board believes that re-electing these incumbent directors will promote stability and continuity and expects that such directors will continue making substantial contributions to the Company by virtue of their familiarity with, and insight into, the Company's affairs accumulated during their tenure.

All of the nominees have indicated a willingness to continue serving as directors, but if any of them should decline or be unable to act as a director, the proxy holders will vote for the election of another person or persons as the Board of Directors recommends. The Company has no reason to believe that any nominee will be unavailable.

Nominees for Director

The following persons have been nominated by the Board of Directors for re-election to the Board of Directors at the Annual Meeting:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Gosse B. Bruinsma, M.D.	50	Chief Executive Officer, President & Chief Operating Officer; Director; President of Axonyx Europe BV
Marvin S. Hausman, M.D.....	63	Chairman and Director
Louis G. Cornacchia (1)(2)(3)	71	Director
Steven H. Ferris, Ph.D. (1)(2)(3)	61	Director
Ralph Snyderman, M.D.....	65	Director
Steven B. Ratoff.....	62	Director

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- (1) Member of the Compensation Committee
 - (2) Member of the Audit Committee
 - (3) Member of the Nominating Committee

Gosse B. Bruinsma, M.D. Gosse Bruinsma has been a director of Axonyx Inc. since June 2001. He has served as President of Axonyx Europe BV since its formation in October 2000. Dr. Bruinsma has served as the Chief Operating Officer of Axonyx since February 2001 and was Treasurer of Axonyx until September 2003. On March 3, 2005, we announced that Dr. Bruinsma has become the CEO of our company. In September 2003, Dr. Bruinsma was appointed President of Axonyx Inc. Dr. Bruinsma has over 15 years experience in the medical, pharmaceutical and biotechnology fields. Dr. Bruinsma received his undergraduate degree from McGill University, Montreal and received his medical degree from the University of Leiden, the Netherlands. He joined the pharmaceutical industry to become European Medical Director for Zambon, Milan. He subsequently joined the international contract research organization, ClinTrials Research, to become their Vice President for Medical and Regulatory Affairs. In September 1995 Dr. Bruinsma joined Forest Laboratories in New York as Medical Director, with medical responsibility for their anti-hypertensive product launch, HRT program, Cervidil®, and their urological disease projects. From September 1997 to 1999 Dr. Bruinsma was General Manager and Vice-President Development for Chrysalis Clinical Services Europe based in Switzerland. From November 1999 until he joined Axonyx Europe BV, Dr Bruinsma was the Vice President Development for Crucell BV (formerly IntroGene), a biotechnology company based in the Netherlands.

Marvin S. Hausman, M.D. On March 3, 2005 Dr. Hausman resigned as Chief Executive Officer, but remains Chairman of the Board. Marvin Hausman had served as a director and President & CEO of Axonyx since January 1997. Dr. Hausman was a co-founder of Medco Research Inc., a pharmaceutical biotechnology company specializing in adenosine products. He has thirty years experience in drug development and clinical care. Dr. Hausman received his medical degree from New York University School of Medicine in 1967 and has done residencies in General Surgery at Mt. Sinai Hospital in New York, and in Urological Surgery at U.C.L.A. Medical Center in Los Angeles. He also worked as a Research Associate at the National Institutes of Health, Bethesda, Maryland. He has been a Lecturer, Clinical Instructor and Attending Surgeon at the U.C.L.A. Medical Center Division of Urology and Cedars-Sinai Medical Center, Los Angeles. He has been a Consultant on Clinical/Pharmaceutical Research to various pharmaceutical companies, including Bristol-Myers International, Mead-Johnson Pharmaceutical Company, Medco Research, Inc., and E.R. Squibb. Since October 1995 Dr. Hausman has been the President of Northwest Medical Research Partners, Inc., a medical technology and transfer company. Dr. Hausman has served on the board of directors of Oxis International, Inc. ("Oxis") from March 2002 to November 2003, and from August 2004 to the present. He was a member of the board of directors of Medco Research, Inc. from inception (1978) through 1992 and from May 1996 to July 1998. Dr. Hausman was a member of the board of directors of Regent Assisted Living, Inc., a company specializing in building assisted living centers including care of senile dementia residents, from March 1996 to April 2001. Dr. Hausman currently serves as Chairman of the Board of Oxis, in which our company holds a 34% interest.

Louis G. Cornacchia Mr. Cornacchia has served as a director of Axonyx since February 21, 2003. Louis Cornacchia has extensive experience in managing several engineering consultancy companies. Louis Cornacchia received a bachelors in Electrical Engineering from Manhattan College in 1955. Between 1955 and 1963, Mr. Cornacchia was employed as an RF engineer at Hazeltine Electronics Corp., at the Loral Systems Design Team where he worked on design of countermeasures/reconnaissance systems, and subsequently was employed as Chief Engineer at Victory Electronics developing light imaging scopes for the U.S. Army. In 1963 Mr. Cornacchia joined Norden Systems where he worked as a Test Equipment Manager for the F111D avionics program. In 1969, Mr. Cornacchia formed Collins Consultants International, Ltd., an engineering consultancy providing services to Norden Systems and multiple defense engineering companies. In 1974, Mr. Cornacchia formed Charger Tech Services, another engineering services company. In 1987, Mr. Cornacchia formed Scinetics, an engineering consultancy that provides microwave wireless engineering services. Scinetics provides engineering services for mobile cellular and PCS wireless companies, assisting them in obtaining approvals for seamless wireless networks. Mr. Cornacchia is presently the President of Scinetics. Mr. Cornacchia has also served as Chairman of the Board of Directors of Reliance Bank, White Plains, New York (1992-1995) and as a member of the Advisory Board of Patriot National Bank, Stamford, Connecticut (1995-2000).

Steven H. Ferris, Ph.D. Dr. Ferris has served as a director of Axonyx since January 6, 2003. Dr. Ferris is a neuropsychologist, psychopharmacologist, and gerontologist who has been studying brain aging and Alzheimer's disease for over thirty years. Dr. Ferris is the Friedman Professor of the Alzheimer's Disease Center in the Department of Psychiatry at New York University (NYU) School of Medicine, Executive Director of NYU's

Silberstein Institute for Aging and Dementia and Principal Investigator of their Alzheimer's Disease Center. Dr. Ferris has been at the NYU School of Medicine since 1973, where he has conducted a major research program focusing on cognitive assessment, early diagnosis and treatment of brain aging and Alzheimer's disease. He has served as the Associate Editor in Chief of *Alzheimer Disease and Associated Disorders*, is a member of the Medical and Scientific Affairs Council of the national *Alzheimer's Association*, has served on several NIH peer review panels, and has been a member of the FDA Advisory Committee which reviews new drugs for Alzheimer's disease. He has conducted more than 50 clinical trials in aging and dementia and has been a consultant to numerous pharmaceutical companies who are developing new treatments for Alzheimer's disease.

Ralph Snyderman, M.D. Dr. Ralph Snyderman was appointed a Director of the Company effective March 8, 2004. Dr. Snyderman is currently Chancellor Emeritus at Duke University. Previously, he served as Chancellor for Health Affairs, Executive Dean of the School of Medicine, and James B. Duke Professor of Medicine, Duke University Medical Center and President and Chief Executive Officer of the Duke University Health System, one of the few fully integrated health systems in the country. Additionally, Dr. Snyderman serves as a member of the board of directors of Proctor and Gamble Inc., Cardiome Pharma Corporation, and SAIC. Dr. Snyderman received his M.D., magna cum laude, in 1965 from the Downstate Medical Center of the State University of New York and he served his internship and residency in medicine at Duke. Pre-eminent in his field of immunology, Dr. Snyderman is internationally recognized for his research contributions to our understanding of inflammation that have led to numerous important discoveries published in nearly 350 manuscripts over the last 25 years.

Steven B. Ratoff Mr. Ratoff joined the Axonyx Board of Directors on May 5, 2005. He has served as a director of InKine Pharmaceutical Company Inc. since February 1998. He has served as a Venture Partner with ProQuest Investments, a health care focused venture capital firm, since December 2004. Mr. Ratoff recently served as Chairman and interim Chief Executive Officer of Cima Labs, Inc., a public specialty pharmaceutical company, from May 2003 until its sale to Cephalon, Inc. in August 2004, and had been a director of Cima Labs since March 1995. He served as a director since 1998 and as President and Chief Executive Officer of MacroMed, Inc. from February 2001 to December 2001. From December 1994 to February 2001, Mr. Ratoff served as Executive Vice President and Chief Financial Officer of Brown-Forman Corporation, a public diversified manufacturer of consumer products. From February 1992 to November 1994, Mr. Ratoff was an investor in a number of small privately held companies. He was Senior Vice President and Chief Financial Officer of the Pharmaceutical Group of Bristol-Myers Squibb from January 1990 to January 1992 and held a number of positions at Bristol-Myers since joining that company in 1975.

There are no family relationships between any of the officers and directors.

Vote required. The holders of Common Stock of the Company are entitled to one vote per share equal to the number of shares held by such person at the close of business on the record date. As there is no cumulative voting, each stockholder shall cast all of his/her votes for each nominee of his/her choice or withhold votes from any or all nominees. Unless a stockholder requests that voting of the proxy be withheld for any one or more of the nominees for directors by so directing on the proxy card, the shares represented by the accompanying proxy will be voted FOR election, as directors, of the above-mentioned six nominees. If any nominee becomes unavailable for any reason (which event is not anticipated) to serve as a director at the time of the meeting, then the shares represented by such proxy may be voted for such other person as may be determined by the holders of such proxy. Directors will be elected at the meeting by a plurality of the votes cast. Directors are to be elected to hold office until the next annual meeting of stockholders and until their successors are elected and qualified, or until their earlier resignation or removal.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT THE STOCKHOLDERS VOTE FOR AND SOLICITS PROXIES IN FAVOR OF THE NOMINEES LISTED ABOVE (ITEM 1 ON THE ENCLOSED PROXY CARD).

INFORMATION CONCERNING THE BOARD OF DIRECTORS AND COMMITTEES THEREOF

During the year ended December 31, 2004, the Board of Directors met on nine occasions and took action by unanimous written consent five times. Other than Michael A. Griffith, who attended one of the two meetings held subsequent to his joining the Board on October 13, 2004, each director attended or participated in 75% or more of the meetings held by the Board of Directors during the period in which he served in 2004, and each committee member attended 75% or more of the committee meetings held during the period in which he served on such committee in 2004. Mr. Griffith resigned from the Board of Directors on April 29, 2005, and Mr. Steven B. Ratoff was elected to the Board of Directors on May 5, 2005.

The Board of Directors created the Compensation, Audit and Nominating Committees at the Board Meeting on January 13, 1999. Prior to that neither the Company nor its predecessors had any Board Committees. In January 2005, our Board also constituted an Executive Committee, which currently consists of Drs. Marvin Hausman, Gosse Bruinsma and Ralph Snyderman.

The Nominating/Governance Committee. The Nominating/Governance Committee (the "Nominating Committee") of the Board of Directors, currently consisting of Messrs. Ferris (chairman), Cornacchia and Vlak, makes proposals to the full Board of Directors concerning the hiring or engagement of directors, officers and certain employee positions. The Nominating Committee met three times in 2004. Following the annual meeting and assuming the election of the nominated directors, the members of the Nominating Committee will be Messrs. Ferris and Cornacchia. Each current member and each prospective member of the Nominating Committee is an "independent director" as defined under the marketplace rules of the Nasdaq Stock Market (Rule 4200).

The Nominating Committee operates pursuant to a written charter, which complies with the corporate governance standards of the Nasdaq Stock Market. A copy of this charter was attached to our proxy statement for the 2004 annual meeting of stockholders as Appendix A thereto. We anticipate that this document will soon be available on our website at www.axonyx.com*.

The Compensation Committee. The Compensation Committee of the Board of Directors, currently consisting of Messrs. Cornacchia (chairman), Ferris and Vlak, administers the Company's 1998 and 2000 Stock Option Plans, and makes proposals to the full Board of Directors for officer compensation programs, including salaries, option grants and other forms of compensation. The Compensation Committee met on nine occasions and acted by unanimous written consent twice in 2004. Following the annual meeting and assuming the election of the nominated directors, the members of the Compensation Committee will be Messrs. Cornacchia and Ferris. Each current member and each prospective member of the Compensation Committee is an "independent director" as defined under the marketplace rules of the Nasdaq Stock Market (Rule 4200).

The Compensation Committee operates pursuant to an amended and restated charter, approved by the Board of Directors on March 30, 2004, that complies with the corporate governance standards of the Nasdaq Stock Market. A copy of this charter was attached to our proxy statement for the 2004 annual meeting of stockholders as Appendix B thereto. We anticipate that this document will soon be available on our website at www.axonyx.com*.

Compensation Committee Interlocks and Insider Participation. There are no Compensation Committee interlocks.

The Audit Committee. The Audit Committee of the Board of Directors, currently consisting of Messrs. Vlak (chairman), Cornacchia and Ferris, recommends the firm to be employed as the Company's independent public accountants, and oversees the Company's audit activities and certain financial matters to protect against improper and unsound practices and to furnish adequate protection to all assets and records. The Audit Committee met on five occasions in 2004. Following the annual meeting and assuming the election of the nominated directors, the members of the Audit Committee will be Messrs. Cornacchia and Ferris, and there will be one vacancy. The Company anticipates that at the first meeting of the Board immediately following the annual meeting it will select an additional independent director from among its remaining independent directors to fill the vacancy on the Audit Committee.

* This website address is not intended to function as a hyperlink, and the information contained on the Company's website is not intended to be part of this proxy statement. The foregoing applies to all references in this proxy statement to the Company's website.

Each current member of the Audit Committee is an "independent director" as defined under the marketplace rules of the Nasdaq Stock Market (Rule 4200). Each prospective member of the committee will meet such definition and, in addition, will also meet the additional independence requirements for audit committees specified by Rule 10A-3 under the Securities Exchange Act of 1934. The Board of Directors has determined that Dr. Vlak qualifies as an "audit committee financial expert" as defined by the Securities and Exchange Commission. Following the annual meeting and assuming the election of the nominated directors, the Audit Committee will have one vacancy and will not have an audit committee financial expert. The Company anticipates that at the first meeting of the Board immediately following the annual meeting it will select an additional independent director who qualifies as an "audit committee financial expert" as defined by the Securities and Exchange Commission from among its remaining independent directors to fill the vacancy on the Audit Committee.

The Audit Committee operates under an amended and restated charter, approved by the Board of Directors on September 23, 2003. A copy of this charter was attached to our proxy statement for the 2004 annual meeting of stockholders as Appendix C thereto. We anticipate that this document will soon be available on our website at www.axonyx.com.

Compensation of Directors

Directors who are also executive officers of the Company are not paid additional compensation for serving as directors. In December 2004 the Company adopted the following policy to compensate outside directors:

The chairman of the Audit Committee receives compensation of \$25,000 annually. The chairmen of the Compensation Committee and the Nominating/Governance Committee each receive compensation of \$15,000 annually. The chairman of the now-defunct Scientific Advisory Committee (which was subsumed into the Executive Committee in 2005) received compensation of \$12,500. Directors will also receive \$2,500 for each board or committee meeting they attend either in person or by telephone if the duration of the meeting exceeds 2 hours. Directors will receive \$1,000 for each board or committee meeting they attend by telephone if the duration of the meeting is less than 2 hours. In addition, we have agreed to reimburse our directors for reasonable expenses incurred in attending meetings of the board of directors and its committees.

Outside directors may be granted stock options on a discretionary basis. In 2004, Dr. Steven Ferris, Dr. Gerard Vlak and Mr. Louis Cornacchia received 50,000 stock options each. Mr. Michael Griffith received 100,000 stock options. Dr. Snyderman received 150,000 stock options.

Director Attendance At Annual Meeting

The Company has adopted a policy encouraging members of the Board of Directors to attend annual meetings. Last year, all of the directors attended the annual meeting.

CORPORATE GOVERNANCE MATTERS

Corporate Governance Principles

We have adopted corporate governance principles to promote the effective functioning of our board. You can access our Corporate Governance Charter on our website at www.axonyx.com.

The policies described in our Corporate Governance Charter and in this proxy statement are intended to set forth general guidance for the functioning of our Board and should not be viewed as a set of legally binding obligations. The Board may, from time to time, modify these principles and policies or approve deviations therefrom as it deems appropriate.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics for our employees, officers and directors. We anticipate that this document will soon be available on our website at www.axonyx.com. This code constitutes a "code of ethics" as defined by the rules of the Securities and Exchange Commission. This code also contains "whistle blower" procedures adopted by our audit committee regarding the receipt, retention and treatment of complaints related to

accounting, internal accounting controls or auditing matters and procedures for confidential anonymous employee complaints related to questionable accounting or auditing matters.

Director Independence

The revised marketplace rules of the Nasdaq Stock Market require that a majority of a company's directors be independent.

We currently have five "independent directors" as defined under the marketplace rules of the Nasdaq Stock Market (Rule 4200), and two non-independent directors. As of the annual meeting date, and assuming election of the directors nominated hereby (one of our current independent directors, Gerard J. Vlak, Ph.D., is not standing for re-election), we will continue to have a majority of independent directors and be in full compliance with the revised marketplace rules of the Nasdaq Stock Market. In assessing director independence, we follow the criteria of the Nasdaq Stock Market. Our current independent directors are: Louis G. Cornacchia, Steven H. Ferris, Ph.D., Gerard J. Vlak, Ph.D, Ralph Snyderman, M.D., and Steven B. Ratoff.

Director Nomination Process

General

The Board has established a Nominating/Governance Committee as described above. The responsibilities of the Nominating/Governance Committee include among others: (i) identifying individuals qualified to become Board members; (ii) recommending to the Board those individuals that should be nominees for election or re-election to the Board or otherwise appointed to the Board (with authority for final approval remaining with the Board); and (iii) developing criteria for evaluating prospective candidates to the Board.

Process For Identifying and Evaluating Candidates

The Nominating/Governance Committee may identify potential Board candidates from a variety of sources, including recommendations from current directors or management or any other source the Nominating/Governance Committee deems appropriate. The Nominating/Governance Committee may also engage a search firm or a consultant to assist it in identifying, screening and evaluating potential candidates. The Nominating/Governance Committee has been given sole authority to retain and terminate any such search firm or consultant.

In considering candidates for the Board, the Nominating/Governance Committee evaluates the entirety of each candidate's credentials. The Nominating/Governance Committee considers, among other things: (i) business or other relevant experience; (ii) expertise, skills and knowledge; (iii) integrity and reputation; (iv) the extent to which the candidate will enhance the objective of having directors with diverse viewpoints, backgrounds, expertise, skills and experience; (v) willingness and ability to commit sufficient time to Board responsibilities; and (vi) qualification to serve on specialized Board committees — such as the audit committee or compensation committee.

The Nominating/Governance Committee is in the process of developing procedures for submission and evaluation of stockholder recommendations for potential Board candidates.

Communications with the Board of Directors

The Board desires that the views of stockholders will be heard by the Board, its committees or individual directors, as applicable, and that appropriate responses will be provided to stockholders on a timely basis. The Board believes that informal communications are currently sufficient to communicate questions, comments and observations that could be useful to the Board. However, stockholders wishing to formally communicate with the Board may send communications directly to the Company, at 500 Seventh Avenue, 10th Floor, New York, New York 10018, Attention: Corporate Secretary. Such communications will be screened by the Corporate Secretary for appropriateness before either forwarding to or notifying the members of the Board of receipt of a communication.

Please note that the foregoing procedure does not apply to (i) stockholder proposals pursuant to Exchange Act Rule 14a-8 and communications made in connection with such proposals or (ii) service of process or any other notice in a legal proceeding. For information concerning stockholder proposals, see "—Stockholder Proposals For The 2006 Annual Meeting."

PROPOSAL 2
RATIFICATION OF APPOINTMENT OF EISNER LLP
AS INDEPENDENT AUDITORS OF THE COMPANY

Eisner LLP (formerly Richard A. Eisner & Company, LLP) has served as the Company's independent accountants since 1998. On March 30, 2005, the Board of Directors, subject to stockholder ratification, approved the continued appointment of Eisner LLP, independent auditors, to audit the accounts of the Company for the 2005 fiscal year.

The Audit Committee intends to meet with Eisner LLP in 2005 on a quarterly or more frequent basis. At such times, the Audit Committee will review the services performed by Eisner LLP, as well as the fees charged for such services.

A representative of Eisner LLP is expected to be present at the Annual Meeting and will have an opportunity to make a statement if he or she desires. The representative is also expected to be available to respond to appropriate questions from stockholders.

Fees Billed to the Company by Eisner LLP during Fiscal Years 2004 and 2003.

Set forth below is certain information concerning fees billed to us by Eisner LLP in respect of services provided in 2004 and 2003. As indicated below, in addition to auditing and reviewing our financial statements, Eisner LLP provided us with other services in 2004 and 2003. The audit committee has determined that the provision of these other services is compatible with maintaining the independence of Eisner LLP.

Audit Fees. Aggregate fees billed for professional services rendered by Eisner LLP in connection with its audit of the Company's consolidated financial statements as of and for the years ended December 31, 2004, and 2003, its reviews of the Company's unaudited condensed consolidated interim financial statements, and for SEC consultations and filings were \$153,000 and \$75,000, respectively.

Audit-Related Fees. The audit-related fees billed for professional services rendered by Eisner LLP for the years ended December 31, 2004, and 2003 were \$26,500 and \$1,400, respectively. These fees were primarily for Sarbanes-Oxley compliance.

Tax Fees. Aggregate fees billed for professional services rendered by Eisner LLP in connection with its income tax compliance and related tax services for the years ended December 31, 2004, and 2003 were \$11,000 and \$14,000, respectively. These tax fees included (1) tax return preparation fee, (2) New York City desk audit and amended return and (3) assistance with the filing of a withdrawal from Connecticut.

All Other Fees. There were no other professional services rendered to us by Eisner LLP in 2004 or 2003.

Policy on Audit Committee Pre-Approval of Audit and Non-Audit Services of Independent Auditor

The charter of the audit committee requires that the committee pre-approve all auditing services and permitted non-audit services (including the fees and terms thereof) to be performed for the company by its independent auditor, subject to any exception permitted by law or regulation. The Audit Committee pre-approved all auditing services and permitted non-audit services rendered by Eisner LLP in 2004.

Vote required. Submission of the appointment to stockholder approval is not required. However, the Board of Directors will reconsider the appointment if it is not approved by stockholders. The appointment will be deemed ratified if a majority of the shares of Common Stock present, either in person or by proxy, and voting on the matter, votes in favor of the proposal.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT THE STOCKHOLDERS VOTE FOR THE RATIFICATION OF EISNER LLP AS INDEPENDENT AUDITORS OF THE COMPANY'S FINANCIAL STATEMENTS FOR THE FISCAL YEAR ENDING DECEMBER 31, 2005 (ITEM 2 ON THE ENCLOSED PROXY CARD).

**REPORT OF THE AUDIT COMMITTEE
OF THE BOARD OF DIRECTORS**

The following is the report of the Audit Committee of the Board of Directors of Axonyx with respect to Axonyx's audited financial statements for the fiscal year ended December 31, 2004, included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 16, 2005. The information contained in this report shall not be deemed to be "soliciting material" or to be "filed" with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Company specifically incorporates it by reference in such filing.

Review With Management

The members of the Audit Committee reviewed and discussed the audited financial statements with certain members of the management of the Company.

Review and Discussions With Independent Accountants

The Audit Committee of the Board of Directors of Axonyx met on March 2, 2005 to review the financial statements for the fiscal year ended December 31, 2004 audited by Eisner LLP, Axonyx's independent auditors. The Audit Committee discussed with a representative of Eisner LLP the matters required to be discussed by SAS 61. The Audit Committee received the written disclosures and the letter from Eisner LLP required by Independence Standards Board Standard No. 1 and has discussed with Eisner LLP its independence.

Conclusion

Based on the above review and discussions, the Audit Committee recommended to the Board of Directors that the audited financial statements for the fiscal year ended December 31, 2004 be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2004 for filing with the Securities and Exchange Commission.

The Audit Committee of the Board of Directors:

Gerard J. Vlak, Ph.D., Chairman
Louis G. Cornacchia
Steven H. Ferris, Ph.D.

EXECUTIVE COMPENSATION

Executive Officers

The executive officers of the Company are Gosse B. Bruinsma, M.D., Chief Executive Officer, President and Chief Operating Officer (and President of Axonyx Europe BV), and S. Colin Neill, Chief Financial Officer, Treasurer and Secretary.

Summary Compensation

The table below sets forth the aggregate annual and long-term compensation paid by us during our last three fiscal years ended December 31, 2004, December 31, 2003 and December 31, 2002 to our Chief Executive Officer and each of the highest paid executive officers of Axonyx whose annual salary and bonus for fiscal year 2004 exceeded \$100,000 (collectively, the "Named Executive Officers").

Annual Compensation (5)

<u>Name and Principal Occupation</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)</u>	<u>Other (\$)</u>	<u>Long term Compensation Awards Securities underlying Options (#)</u>
Marvin S. Hausman Dir., Chairman & CEO	2004	\$394,375	\$200,000	\$54,376(5)	200,000
	2003	\$250,000	\$175,000	\$31,719	325,000(4)
	2002	\$246,000	—	\$54,376	75,000
Gosse B. Bruinsma Dir., President & COO (1)	2004	\$372,000	\$150,000	\$31,000	100,000
	2003	\$253,000	\$100,000	\$28,250	300,000(4)
	2002	\$197,000	—	\$23,750	140,000
S. Colin Neill CFO, Sec. & Treas. (2)	2004	\$212,000	\$100,000	\$10,000	50,000
	2003	\$ 52,000	\$ 10,000	\$ 2,915	210,000(4)

- (1) Gosse B. Bruinsma, M.D. became an employee of Axonyx in October 2000. Dr. Bruinsma resides and operates from the Axonyx Europe BV offices in Leiden, The Netherlands and is therefore compensated in the local currency, i.e. Euros. Dr. Bruinsma's salary for 2004 was Euro 300,000 and his expense allowance was Euro 25,000. These amounts are reflected in the table above at the average dollar/euro exchange rate of 1.24 for 2004, 1.13 for 2003, and 0.95 for 2002. Dr. Bruinsma was appointed Chief Executive Officer on March 3, 2005.
- (2) S. Colin Neill became an employee of Axonyx in September 2003. Mr. Neill was reimbursed \$10,000 for various business expenses including life insurance.
- (3) No Named Executive Officer was paid other annual compensation in an amount exceeding the lesser of either \$50,000 or 10% of the total annual salary and bonus for the Named Executive Officer.
- (4) The number of options granted for certain Executive Officers in 2003 have been adjusted to include options granted in 2003 under our 2000 Stock Option Plan which were contingent upon the January 1, 2004 increase in the number of shares reserved for issuance under the 2000 Stock Option Plan by 750,000 shares per the evergreen provision. The increase in options granted for each Executive Officer in 2003 due to this adjustment are as follows: Marvin S. Hausman, M.D. 125,000; Gosse B. Bruinsma, M.D. 100,000; S. Colin Neill 93,620.
- (5) The Company reimbursed Dr. Hausman to cover costs of maintaining an office and related support costs in Portland, Oregon. Dr. Hausman stepped down as Chief Executive Officer effective March 3, 2005 but remains Chairman of the Board.

B. Option Grants in Fiscal Year 2004

The following table sets forth certain information with respect to option grants to our Named Executive Officers in 2004. All of the grants were made under the Axonyx 2000 Stock Option Plan. We have not granted any stock appreciation rights.

Name	Option Grants in Fiscal Year 2004				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term (1)	
	Individual Grants			Expiration date	5% (\$)	10% (\$)
	Number of securities underlying Options Granted (#)	Percent of total options granted to employees in fiscal year	Exercise or base price (\$/Sh)			
Marvin S. Hausman (2)	200,000	57.1%	\$7.03	12/7/14	\$884,226	\$2,240,802
Gosse B. Bruinsma (3).....	100,000	28.6%	\$7.03	12/7/14	\$442,113	\$1,120,401
S. Colin Neill (4).....	50,000	14.3%	\$7.03	12/7/14	\$221,056	\$ 560,200

- (1) These amounts represent hypothetical gains that could be achieved for the respective options at the end of the ten year option term. The assumed 5% and 10% rates of compounded stock price appreciation are mandated by rules of the Securities and Exchange Commission and do not represent Axonyx's estimate of the future market price of the common stock.
- (2) On December 7, 2004, Axonyx granted 200,000 Incentive Stock Options exercisable at \$7.03 per share to Marvin S. Hausman, M.D., with 50,000 options vesting on December 7, 2004, 2005, 2006 and 2007.
- (3) On December 7, 2004, Axonyx granted 100,000 Incentive Stock Options exercisable at \$7.03 per share to Gosse B. Bruinsma, M.D., with 25,000 options vesting on December 7, 2004, 2005, 2006 and 2007.
- (4) On December 7, 2004 Axonyx granted 50,000 Incentive Stock Options exercisable at \$7.03 per share to S. Colin Neill, with 12,500 options vesting on December 7, 2004, 2005, 2006 and 2007.

C. Aggregate Option Exercises in Fiscal Year 2004 Year End Option Values

The following table sets forth the number and value of unexercised options held by the Named Executive Officers as of December 31, 2004.

Name	Number of shares acquired on exercise	Value (\$) Realized	Number of securities underlying unexercised options at fiscal year end # (1)	Value of unexercised in-the-money options at fiscal year end (\$) (2)
			Exercisable/ unexercisable	Exercisable/ unexercisable
Marvin S. Hausman,..... M.D., Chairman & CEO (3)	175,000	\$ 845,000	562,500/ 362,500	\$769,875/ \$815,875
Gosse B. Bruinsma, M.D., Pres. & COO (3)	215,000	\$1,064,000	435,000/ 290,000	\$699,900/ \$846,850
S. Colin Neill, C.F.O.	—	—	117,500/ 142,500	\$256,950/ \$256,950

- (1) The number of options granted for certain Executive Officers in 2003 have been adjusted to include options granted in 2003 under our 2000 Stock Option Plan which were contingent upon the January 1, 2004 increase in the number of shares reserved for issuance under the 2000 Stock Option Plan by 750,000 shares per the evergreen provision. The increase in options granted for each Executive Officer in 2003 due to this adjustment are as follows: Marvin S. Hausman, M.D. 125,000; Gosse B. Bruinsma, M.D. 100,000; S. Colin Neill 93,620.
- (2) Dollar amounts reflect the net values of outstanding stock options computed as the difference between \$6.20 (the fair market value at December 31, 2004) and the exercise price of the options.
- (3) Dr. Bruinsma replaced Dr. Hausman as CEO effective March 3, 2005.

Employment Contracts with Executive Officers and Termination of Employment and Change-in-Control Arrangements

Axonyx does not have employment contracts with any of its Named Executive Officers, except as follows:

Gosse B. Bruinsma, M.D., President, Chief Executive Officer, Chief Operating Officer and Director. On September 21, 2002 Axonyx signed an Employment Agreement with Dr. Bruinsma under which Dr. Bruinsma agreed to serve as President of Axonyx Europe BV, a wholly owned subsidiary of Axonyx Inc, and Chief Operating Officer of Axonyx Inc. This agreement has been renewed and now extends through September 2006. The salary has been determined at Euro 330,000 and the expense reimbursement at Euro 25,000, including for the use of a home office and personal equipment, health insurance, disability insurance, life insurance, pension distribution and auto lease premium.

In March 2004, following approval of the Compensation Committee and the Board, Axonyx entered into change of control agreements with Marvin S. Hausman, Gosse Bruinsma and S. Colin Neill. Each agreement provides that if the executive's employment is terminated without "cause," as defined in the agreement, within 90 days prior to, or one year following, a "change of control," he will receive severance pay equal to 200% of his annual base salary for the then-current year, plus the greater of the annual bonus he received for the prior year or the then-current annual target bonus. Such payments are also required to be made in connection with a change of control if the executive has "good reason" to terminate his employment, as defined in the agreement. A "change of control" involves an acquisition of at least 50% of the voting power of the Company's securities, a change in at least a majority of the members of the current Board of Directors, or approval by the Board of Directors or stockholders of the Company of a transaction where such change of voting control or composition of the Board would occur, where the Company would be liquidated or where all or substantially all of its assets would be sold.

In addition, all options granted under the 1998 Stock Option Plan and the 2000 Stock Option Plan, including those to its executive officers, provide for accelerated vesting upon a change in control, among other events.

Equity Compensation Plan Information

The following table sets forth information about the common stock available for issuance under compensatory plans and arrangements as of December 31, 2004.

<u>Plan Category</u>	<u>(a)</u> <u>Number of securities to be</u> <u>issued upon exercise of</u> <u>outstanding options,</u> <u>warrants</u> <u>and rights.</u>	<u>(b)</u> <u>Weighted-average</u> <u>exercise price of</u> <u>outstanding options,</u> <u>warrants, and rights</u>	<u>(c)</u> <u>Number of securities</u> <u>remaining available for future</u> <u>issuance under equity</u> <u>compensation plans (excluding</u> <u>securities reflected</u> <u>in column (a))</u>
Equity compensation plan approved by security holders (1).....	983,600	\$5.96	—
Equity compensation plan approved by security holders (2).....	3,450,500	\$4.21	3,392,380
Equity compensation plans not approved by security holders.....	<u>342,500(3)</u>	<u>\$4.51</u>	<u>—</u>
Total.....	<u>4,776,600</u>	<u>\$4.60</u>	<u>3,392,380</u>

- (1) As of April 29, 2005, we have granted options to purchase an aggregate of 1,084,000 shares of common stock under our 1998 Stock Option Plan. As of December 31, 2004, no options were available for future grant under the 1998 plan. The plan terminated on January 15, 2003.
- (2) As of April 29, 2005, we have granted options to purchase an aggregate of 4,083,000 shares of common stock under our 2000 Stock Option Plan.
- (3) We have granted an aggregate of 342,500 options to consultants and advisors outside of our 1998 and 2000 stock option plans.

Compensation Committee Report on Executive Compensation

The Compensation Committee of the Board of Directors, which is composed of outside directors, is responsible for setting and administering the policies and programs that govern compensation. The Compensation Committee was originally formed in January 1999. Prior to that time no executive compensation, other than limited consultant fees, was paid. For 2004, the Company's executive compensation consisted of two components: (1) an annual component, i.e., salaries, and the potential for year end bonuses, and (2) a long-term component, i.e., stock options. The Compensation Committee bases its decisions on executive compensation based on individual assessments of the amount of compensation required to attract individuals to fill positions in the Company and motivate those individuals to focus on achieving the objectives of the Company. The Compensation Committee seeks to reward the management team if the Company achieves its corporate objectives, and it also recognizes meaningful differences in individual performance and offers the opportunity for executives to earn rewards when merited by individual performance.

Annual Component. Salaries for executive officers are determined by the Committee with reference to the job description and a general assessment of the executive's performance, experience and potential. Year-end bonuses may be granted subject to an assessment of an executive's performance against established objectives. The Committee establishes these salaries annually or semi-annually, depending upon the individual.

Long-Term Component. The Compensation Committee awarded stock options or contingent stock options to its executive officers in December 2004 based on the Committee's assessment of the accomplishment of corporate and individual objectives. These options provide the opportunity to buy a number of shares of the Company's Common Stock at a price equal to the market price of the stock on the date of Committee approval of the grant. These options are generally subject to a three-year vesting schedule, so that they become exercisable in annual installments during the participant's period of service with the Company. The Committee believes that, because these options gain value only to the extent that the price of the Company's Common Stock increases above the option exercise price during the term of the optionee's service, management's equity participation offers a significant incentive and helps to create a long-term partnership between management/owners and other stockholders. The Committee believes that the grant of stock options should reflect the Company's success in meeting objectives established by the Board, each individual officer's ability to attain such objectives and such officer's contribution towards the attainment of past objectives.

Compliance with Internal Revenue Code Section 162(m). As a result of Section 162(m) of the Internal Revenue Code of 1986, as amended, the Company will not be allowed a federal income tax deduction for compensation paid to certain executive officers, to the extent that compensation exceeds \$1 million per officer in any one calendar year. This limitation will apply to all compensation which is not considered to be performance-based. Compensation which does qualify as performance-based compensation will not have to be taken into account for purposes of this limitation. The Amended and Restated 2000 Stock Option Plan (as well as the Second Amended and Restated 2000 Stock Option Plan), contains certain provisions which permit the Company, on a grant-by-grant basis, to make awards of stock options (with an exercise price equal to or greater than fair market value of the Common Stock on the date of grant) that will qualify as performance-based compensation so that any compensation deemed paid in connection with those options will be excluded from the 162(m) limitation. The Company's 1998 Stock Option Plan does not contain provisions to qualify stock options under that plan as performance-based compensation. The Compensation Committee considers this among all factors taken into account when setting compensation policy and making individual compensation decisions.

The Compensation Committee does not expect that the compensation to be paid to any of the Company's executive officers for 2004 will exceed the \$1 million limit per officer; however, it is possible that in the future the deductibility of compensation may be limited by Internal Revenue Code Section 162(m).

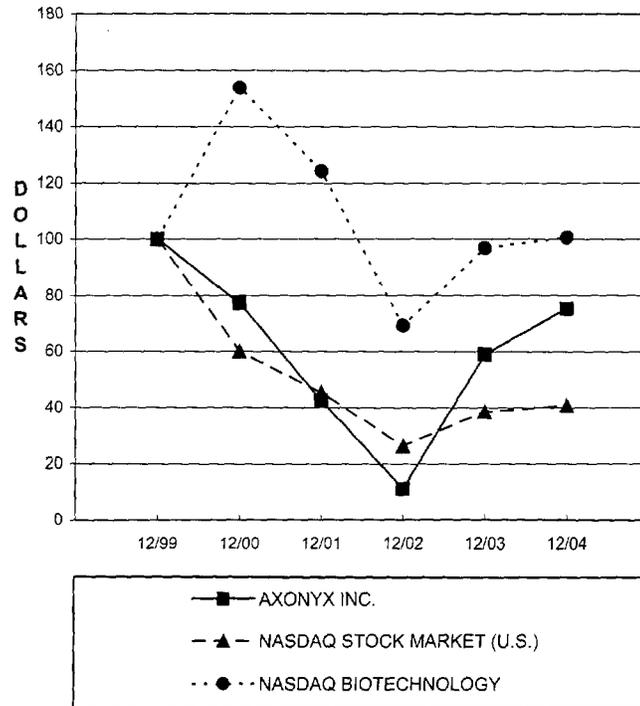
The Compensation Committee of the Board of Directors:

Louis G. Cornacchia, Chairman
Steven H. Ferris, Ph.D.
Gerard J. Vlsek, Ph.D.

PERFORMANCE GRAPH

Set forth below is a graph comparing the cumulative total stockholder return of \$100 invested in our Common Stock on December 31, 1999 through December 31, 2004 with the cumulative total return of \$100 invested in the Nasdaq Stock Market (U.S.) Index and the Nasdaq Biotechnology Index calculated similarly for the same period.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
 AMONG AXONYX INC., THE NASDAQ STOCK MARKET (U.S.) INDEX
 AND THE NASDAQ BIOTECHNOLOGY INDEX



* \$100 invested on 12/31/99 in stock or index—
 including reinvestment of dividends.
 Fiscal year ending December 31.

NOTWITHSTANDING ANYTHING TO THE CONTRARY SET FORTH IN ANY OF THE COMPANY'S PREVIOUS FILINGS MADE UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, THAT MIGHT INCORPORATE FUTURE FILINGS MADE BY THE COMPANY UNDER THOSE STATUTES, THE COMPENSATION COMMITTEE REPORT, THE AUDIT COMMITTEE REPORT, AUDIT COMMITTEE CHARTER, REFERENCE TO THE INDEPENDENCE OF THE AUDIT COMMITTEE MEMBERS AND THE STOCK PERFORMANCE GRAPH ARE NOT DEEMED FILED WITH THE SECURITIES AND EXCHANGE COMMISSION AND SHALL NOT BE DEEMED INCORPORATED BY REFERENCE INTO ANY OF THOSE PRIOR FILINGS OR INTO ANY FUTURE FILINGS MADE BY THE COMPANY UNDER THOSE STATUTES.

Section 16(a) Beneficial Ownership Reporting Compliance.

No person who, during the fiscal year ended December 31, 2004, was a director or officer of the Company, or beneficial owner of more than ten percent of the Company's Common Stock, which is the only class of securities of the Company registered under Section 12 of the Securities Exchange Act of 1934 (the "Act"), failed to file on a timely basis reports required by Section 16 of the Act during such fiscal year. The foregoing is based solely upon a review by the Company of Forms 3 and 4 relating the most recent fiscal year as furnished to the Company under Rule 16a-3(d) under the Act, and Forms 5 and amendments thereto furnished to the Company with respect to its most recent fiscal year, and any representation received by the Company from any reporting person that no Form 5 is required.

Security Ownership of Certain Beneficial Owners and Management.

The following table sets forth certain information regarding beneficial ownership of our common stock as of May 5, 2005, unless otherwise indicated, (a) by each person known by us to own beneficially 5% or more of any class of our common stock, (b) by each of our Named Executive Officers and directors and (c) by all executive officers and directors of Axonyx as a group. As of May 5, 2005 there were 53,665,518 shares of our common stock issued and outstanding. The numbers of shares beneficially owned include shares of common stock that the listed beneficial owners have the right to acquire within 60 days of May 5, 2005 upon the exercise of all options and other rights beneficially owned on that date. Unless otherwise noted, we believe that all persons named in the table have sole voting and investment power with respect to all the shares beneficially owned by them.

<u>Name of Beneficial Owner (1)</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percent of Class</u>
Marvin S. Hausman, M.D. (2)	3,002,439	5.53%
Gosse B. Bruinsma, M.D. (3)	510,500	*
S. Colin Neill (4)	117,500	*
Louis G. Cornacchia (5)	263,933	*
Steven H. Ferris, Ph.D. (6)	79,000	*
Gerard J. Vlak, Ph.D. (7)	102,500	*
Ralph Snyderman, M.D. (8)	62,500	*
Steven B. Ratoff	0	N/A
All directors and executive officers (8 persons) as a group	4,138,372	7.49%
HYMF Limited (9)	3,092,630	5.76%
Kilkenny Capital Management, LLC (10)	2,818,735	5.25%

* Less than 1%.

- (1) Unless otherwise indicated, the address of each of the listed beneficial owners identified above is c/o 500 Seventh Avenue, 10th Floor, New York, NY 10018.
- (2) Marvin S. Hausman, M.D. Includes: (i) 2,389,939 shares owned by Dr. Hausman; (ii) 100,000 vested but unexercised options exercisable at \$11.50 per share granted on January 10, 2000, (iii) 150,000 vested but unexercised options exercisable at \$7.91 per share granted on December 15, 2000, and (iv) 200,000 vested but unexercised options exercisable at \$3.16 per share granted on December 11, 2001, (v) 62,500 vested but unexercised options exercisable at \$ 3.61 per share granted on November 18, 2003. This grant was contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, (vi) 50,000 vested but unexercised options exercisable at \$7.03 per share granted on December 7, 2004, and (vii) 50,000 vested but unexercised options exercisable at \$1.18 per share granted on March 17, 2003. Does not include: (i) 3,000 shares gifted to Dr. Hausman's three adult children, with 1,000 to each in October 1999, (ii) 200 shares gifted to Roberta Matta in October 1999, (iii) 5,000 shares gifted to a religious institution in October 2000, (iv) 5,000 shares gifted to six non-affiliate donees in September 2000, (v) 10,550 shares gifted to six non-affiliate donees, including Dr. Hausman's three adult children in July 2001, (vi) 4,300 shares gifted to three non-affiliate donees in October 2001, (vii) 3,000 shares gifted to a non-affiliate donee in October 2001, (viii) 12,300 shares gifted to Dr. Hausman's three adult children and Roberta Matta in December 2001, (ix) 4,717 shares gifted to two non-affiliate donees in December 2001, (x) 8,834 shares gifted to five non-affiliate donees in February 2002, (xi) 4,500 shares gifted to two non-affiliate donees in

March 2002, (xii) 5,832 shares gifted to five non-affiliate donees, (xiii) 16,000 shares gifted to three non-affiliate donees in September 2002, (xiv) 20,000 shares gifted to two non-affiliate donees in February 2003, (xv) 10,000 shares gifted to a non-affiliate donee in March 2003, (xvi) 60,000 shares gifted to an non-affiliated donee in April 2003, and (xvii) 1,000 shares gifted to Roberta Matta in April 2003, and (xviii) 2000 share gifted to a non-affiliated donee, 500 shares gifted to Kevin Matta and 1,000 shares gifted to Roberta Matta in February 2004, (xix) 4,000 shares gifted to two non-affiliated donees in June 2004, (xx) 7,500 shares gifted to three adult children in August 2004, (xxi) 16,350 shares gifted to ten non-affiliated donees in August 2004, (xxii) 180 shares gifted to non-affiliated donees and 50 shares gifted to a family member in October 2004, (xxiii) 1000 shares gifted to Roberta Matta in December 2004, (xxix) 1000 shares gifted to four family members in December 2004, (xv) 50,000 unvested options exercisable at \$3.16 per share granted on December 11, 2001, (xxv) 50,000 unvested options exercisable at \$1.18 granted on March 17, 2003, and (xxvii) 62,500 unvested options exercisable at \$3.61 per share granted on November 18, 2003. This grant was contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, and (xxviii) 150,000 unvested options exercisable at \$7.03 per share granted on December 7, 2004.

- (3) Gosse B. Bruinsma, M.D. Includes: (i) 500 shares owned by Gosse Bruinsma, M.D., (ii) 150,000 vested but unexercised options exercisable at \$9.50 per share granted on October 10, 2000; (iii) 50,000 vested but unexercised options exercisable at \$4.52 per share granted on May 11, 2001; (iv) 160,000 vested but unexercised options exercisable at \$3.16 per share granted on December 11, 2001; (v) 50,000 vested but unexercised options exercisable at \$3.61 per share granted November 18, 2003. This grant was contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, (vi) 25,000 vested but unexercised options exercisable at \$7.03 per share granted December 7, 2004; (vii) 50,000 vested but unexercised options exercisable at \$1.07 per share granted on March 17, 2003; and (viii) 25,000 unvested options exercisable at \$2.89 per share granted on June 11, 2002 that will vest within 60 days. Does not include: (i) 40,000 unvested options exercisable at \$3.16 per share granted on December 11, 2001; (ii) 50,000 unvested options exercisable at \$1.07 per share granted on March 17, 2003; (iii) 50,000 unvested options exercisable at \$3.61 per share granted November 18, 2003. This grant was contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, and (iv) 75,000 unvested options exercisable at \$7.03 per share granted December 7, 2004.
- (4) S. Colin Neill. Includes: (i) 100,000 vested but unexercised options exercisable at \$3.76 granted on September 15, 2003, of which 23,405 options were contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, (ii) 5,000 vested but unexercised option exercisable at \$3.61 granted on November 18, 2003, and (iii) 12,500 vested but unexercised options exercisable at \$7.03 per share granted December 7, 2004. Does not include: (i) 100,000 unvested options exercisable at \$3.76 per share granted on September 15, 2003, of which 70,215 options were contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, (ii) 5,000 unvested options exercisable at \$3.61 per share granted on November 18, 2003, and (iii) 37,500 unvested options exercisable at \$7.03 per share granted December 7, 2004.
- (5) Louis G. Cornacchia. Includes: (i) 138,622 shares owned by Mr. Cornacchia; (ii) 33,311 common stock purchase warrants exercisable at \$0.688 per share purchased in a private placement on December 31, 2002; (iii) 2,000 common stock purchase warrants exercisable at \$11.00 per shares purchased in a private placement on October 25, 1999; (iv) 30,000 vested but unexercised options exercisable at \$0.825 per share granted on February 21, 2003 (v) 25,000 vested but unexercised options exercisable at \$4.24 per share granted September 23, 2003 (vi) 25,000 vested but unexercised options exercisable at \$5.27 per share granted October 12, 2004, and (vii) 10,000 vested but unexercised options exercisable at \$0.825 per share granted on February 21, 2003. Does not include: (i) 10,000 unvested options exercisable at \$0.825 per share granted on February 21, 2003 (ii) 25,000 unvested options exercisable at \$4.24 per share granted September 23, 2003, and (iii) 25,000 unvested options exercisable at \$5.27 per share granted October 12, 2004.
- (6) Steven H. Ferris, Ph.D. Includes: (i) 5,000 vested but unexercised options exercisable at \$7.00 per share granted on March 25, 2000; (ii) 4,000 vested but unexercised options exercisable at \$11.00 per share granted on March 25, 2000 (iii) 10,000 vested but unexercised options exercisable at \$3.06 per share granted on February 15, 2002, (iv) 10,000 vested but unexercised options exercisable at \$1.11 per share granted on January 14, 2003 (v) 25,000 vested but unexercised options exercisable at \$4.24 per share granted September 23, 2003 and (vi) 25,000 vested but unexercised options exercisable at \$5.27 per share granted October 12, 2004. Does not include: (i) 10,000 unvested options exercisable at \$1.11 per share granted on

- January 14, 2003 and (ii) 25,000 unvested options exercisable at \$4.24 per share granted September 23, 2003 and (iii) 25,000 unvested options exercisable at \$5.27 per share granted October 12, 2004.
- (7) Gerard J. Vlak, Ph.D. Includes: (i) 30,000 vested but unexercised options exercisable at \$0.825 per share granted on February 21, 2003 (ii) 27,500 vested but unexercised options exercisable at \$4.24 per share granted September 23, 2003, (iii) 25,000 vested but unexercised options exercisable at \$5.27 per share granted October 12, 2004, and (iv) 10,000 vested but unexercised options exercisable at \$0.825 per share granted on February 21, 2003. Does not include: (i) 20,000 unvested options exercisable at \$0.825 per share granted on February 21, 2003 (ii) 37,500 unvested options exercisable at \$4.24 per share granted September 23, 2003, and (iii) 25,000 unvested options exercisable at \$5.27 per share granted October 12, 2004.
- (8) Ralph Snyderman, M.D. Includes: (i) 12,500 vested but unexercised options exercised at \$7.09 per share granted on March 8, 2004. (ii) 25,000 vested but unexercised options exercisable at \$5.27 per share granted October 12, 2004 (iii) 12,500 vested but unexercised options exercisable at \$7.09 per share granted on March 8, 2004, and (iv) 12,500 vested but unexercised options exercisable at \$7.03 per share granted December 7, 2004. Does not include: (i) 25,000 unvested options exercisable at \$7.09 per share granted on March 8, 2004 (ii) 25,000 unvested options exercisable at \$5.27 per share granted October 12, 2004, and (iii) 37,500 unvested options exercisable at \$7.03 per share granted December 7, 2004.
- (9) HYMF Limited, Walker House Mary Street PO Box 908 GT, George Town, Grand Cayman. This information is based on a Schedule 13G filed by the holder on February 14, 2005, and is as of December 31, 2004. HYMF Limited holds the shares in trust accounts for the economic benefit of the beneficiaries of those accounts. HYMF Limited has sole power to direct the vote of 2,629,791 of the shares, and sole power to dispose or to direct the disposition of 3,092,630 shares.
- (10) Kilkenny Capital Management, LLC, 311 South Wacker Drive, Suite 6350, Chicago, IL 60606. This information is based on a Schedule 13G filed by the holder on February 14, 2005, and is as of December 31, 2004. Kilkenny Capital Management, LLC, is a registered investment advisor, and, together with its controlling members, Michael P. Walsh and Elizabeth R. Foster, has shared voting power and shared dispositive power over the 2,818,735 shares.

Certain Relationships and Related Transactions.

The Company reimburses the Chairman for certain costs incurred in maintaining an office and related support in Portland, Oregon. The amounts of such reimbursements in 2004 and 2003 were approximately \$54,000 and \$32,000, respectively.

OTHER MATTERS

The management of the Company is not aware of any matter to be acted upon at the Annual Meeting other than the matters described above. However, if any other matter properly comes before the Annual Meeting, the proxy holders will vote the proxies thereon in accordance with their best judgment on such matter.

PROXY SOLICITATION

The Company will pay reasonable expenses incurred in forwarding proxy material to the beneficial owners of shares and in obtaining the written instructions of such beneficial owners. This Proxy Statement and the accompanying materials, in addition to being mailed directly to stockholders, will be distributed through brokers, custodians, nominees and other like parties to beneficial owners of shares of Common Stock. The Company will bear the expenses of calling and holding the Annual Meeting and the soliciting of proxies therefor.

The Company may consider the engagement of a proxy solicitation firm. Our directors, officers and employees may also solicit proxies by mail, telephone and personal contact. They will not receive any additional compensation for these activities.

STOCKHOLDER PROPOSALS FOR 2006 ANNUAL MEETING

Proposals which are the proper subject for inclusion in the proxy statement and for consideration at an annual meeting may be presented by stockholders. In order to be eligible to submit a proposal, a stockholder must have continuously held at least \$2,000 in market value, or 1% of the Company's securities entitled to be voted on the proposal at the meeting for at least one year by the date the stockholder submits the proposal. In addition, the stockholder must continue to hold those securities through the date of the meeting. Under current Securities and Exchange Commission rules, to be included in the Company's proxy statement and proxy card, any proposal by a stockholder intended to be presented at the 2006 annual meeting of stockholders must be received by the Company, subject to certain exceptions, no later than January 16, 2006. Any such proposal, including any accompanying supporting statement, may not exceed 500 words. Such proposal should be addressed to the Secretary of the Company, S. Colin Neill. In addition, the proxy solicited by the Board of Directors for the 2006 annual meeting of stockholders will confer discretionary authority to vote on any stockholder proposal raised at the 2006 annual meeting of stockholders that is not described in the 2006 proxy statement unless the Company has received notice of such proposal on or before the close of business on March 31, 2006. However, if the Company determines to change the date of the 2006 annual meeting of stockholders more than 30 days from June 16, 2006, the Company will provide stockholders with a reasonable time before the Company begins to print and mail its proxy materials for the 2006 annual meeting of stockholders in order to allow stockholders an opportunity to make proposals in accordance with the rules and regulations of the Securities and Exchange Commission.

ANNUAL REPORTS

Our 2004 Annual Report to Stockholders, which contains our Annual Report on Form 10-K, including its financial statements for the year ended December 31, 2004, accompanies this proxy statement. The Company's Annual Report on Form 10-K for the year ended December 31, 2004 will also be made available (without exhibits), free of charge, to interested stockholders upon written request to Victoria Trahan, Office Manager, 500 Seventh Avenue, 10th Floor, New York, New York 10018, telephone (212) 645-7704.

BY ORDER OF THE BOARD OF DIRECTORS

/s/ Marvin S. Hausman, M.D.

Marvin S. Hausman, M.D.

Chairman of the Board

May 16, 2005

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

FORM 10-K

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

For the fiscal year ended December 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: 000-25571

AXONYX INC.

500 Seventh Avenue, 10th Floor
New York, New York 10018
Telephone (212) 645-7704

I.R.S. Employer Identification Number: 86-0883978

State or Other jurisdiction of Incorporation or Organization: NEVADA

Securities registered under Section 12(g) of the Exchange Act: COMMON STOCK \$0.001 PAR VALUE

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

The registrant estimates that the aggregate market value of its Common Stock on June 30, 2004, based on the closing price shown on the Nasdaq SmallCap Market on that date of \$5.24, held by its non-affiliates was approximately \$255,400,189.

The number of shares of Common Stock, par value \$0.001, of the Registrant outstanding as of February 28, 2005, was 53,665,518 shares.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

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This Form 10-K contains "forward-looking" statements, as defined in the Private Securities Litigation Reform Act of 1995 that are based on current expectations, estimates and projections. Statements that are not historical facts, including statements about our beliefs and expectations, are forward-looking statements. These statements involve potential risks and uncertainties; therefore, actual results may differ materially. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they were made. We do not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Specifically, with respect to our drug candidate Phenserine, Axonyx cannot assure that the Phase IIb and/or other Phase III clinical trials, amendments thereto or others, if any, with Phenserine will prove successful, that the safety and efficacy profile of Phenserine exhibited in the previous small Phase II and Phase III trials will remain the same, be better or worse in future clinical trials, if any, that the pre-clinical results related to the regulation of beta-APP will be substantiated by the Phenserine Phase IIb clinical trial and that Phenserine will be able to slow the progression of Alzheimer's disease, that the Phase IIb clinical trial data will differentiate Phenserine from the currently marketed drugs, that any efficacy and safety results of a Phase III trial program if pursued, will prove pivotal, that Axonyx will obtain the necessary financing to complete the Phenserine development program, that the Company's development work on Phenserine will support an NDA filing, that the results of Phase III trials will allow Phenserine to be approved by the FDA, that the FDA will grant marketing approval for Phenserine, that if Phenserine is approved by the FDA, it will prove competitive in the market, and that Axonyx will obtain licensing or corporate partnership agreements that will enable successful development of or acceleration of the development of and optimize marketing opportunities for, Phenserine. Axonyx cannot assure that it will be able to advance any of its other potential memory enhancing compounds toward IND status or beyond. Axonyx undertakes no obligation to publicly release the result of any revisions to such forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

We do not undertake to discuss matters relating to our ongoing clinical trials or our regulatory strategies beyond those which have already been made public or discussed herein.

PART I

Item 1. Business

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- A. Recent Events
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A. Recent Events

In January 2004, we completed a private placement for \$50 million of securities through the sale of 9,650,183 shares of common stock at \$5.15 per share with new and existing institutional investors. This placement also involved the acquisition by the investor group of five-year warrants to purchase an additional 2,412,546 shares of our company's stock at an exercise price of \$7.25 per share.

On January 15, 2004, we entered into separate agreements to acquire, at the time, approximately 52% of the outstanding voting stock of OXIS International Inc. (OXIS). Our Chairman and then Chief Executive Officer owns 1,161,532 shares of OXIS common stock, representing at the time of the original acquisitions approximately 4% of the OXIS's voting stock, and, on December 10, 2004 he became acting Chief Executive Officer and acting Chief Financial Officer of OXIS. Those shares of OXIS's common stock owned by our Chairman were not acquired. In June 2004, we loaned OXIS \$1.2 million, which was due and payable within one year or until a qualified financing occurs (whichever is earlier). Interest on this loan accrued at 7% per annum and was payable quarterly. This loan was partially secured by certain assets of OXIS. The loan, in the form of a one-year secured note, was used to continue the advancement of OXIS' oxidative stress programs and other working capital purposes. On January 6, 2005, the \$1.2 million loan, with interest, was repaid to us by OXIS in connection with a \$6.5 million private placement of OXIS's common stock and warrants. In December 2004, OXIS sold common stock and warrants and bridge loans were converted into common stock. As a result, our ownership in OXIS was reduced to 34%, however, we continued to consolidate with OXIS until March 1, 2005, when we no longer controlled the board of directors.

Dr. Ralph Snyderman was appointed a Director of the Company effective March 8, 2004. Dr. Snyderman is currently Chancellor Emeritus at Duke University. Previously, he served as Chancellor for Health Affairs, Executive Dean of the School of Medicine, and James B. Duke Professor of Medicine, Duke University Medical Center and President and Chief Executive Officer of the Duke University Health System, one of the few fully integrated health systems in the country. Additionally, Dr. Snyderman serves as a member of the board of directors of Proctor and Gamble Inc., Cardiome Pharma Corporation, and SAIC.

In May 2004, we completed a private placement for \$20 million of securities through the sale of 3,076,923 shares of common stock at \$6.50 per share with new institutional investors. This placement also involved the acquisition by the investor group of five-year warrants to purchase an additional 923,077 shares of our company's stock at an exercise price of \$8.50 per share.

In July 2004, we signed a non-binding Memorandum of Understanding (MOU) with Serono International, S.A. (NYSE: SRA) for the research and joint development of therapeutic compounds and diagnostic technologies in the field of protein mis-folding disorders such as Parkinson's Disease, Down's Syndrome, Diabetic disorders,

Lou Gehrig's Disease, Alzheimer's Disease, Transmissible Spongiform Encephalopathies (TSE's) i.e. Mad Cow Disease (BSE) and Creutzfeldt Jakob Disease new variant (CJDnv).

The execution of the MOU by the parties was a result of previously disclosed discussions about alternative structures and collaborations to current licensing arrangements covering the amyloid and prion inhibitory peptide technologies.

Since the signing of the MOU, the parties have been in protracted discussions regarding the terms of definitive agreements. We cannot be assured at this time that the due diligence and/or these discussions will result in a mutually satisfactory outcome.

On October 13, 2004, we appointed Michael A. Griffith as a Director of Axonyx. Mr. Griffith is currently Chief Executive Officer of GPD Pharma, a contract pharmaceutical company. Mr. Griffith was formerly Chairman and Chief Executive Officer of ChiRex Inc. (NASDAQ: CHRX), a contract pharmaceutical research and development and contract manufacturer of active pharmaceutical ingredients. Mr. Griffith is currently Chairman of the Board of Directors of Centru Financial Corporation (AMEX: CFF), an Illinois state-chartered bank holding company with over \$600 million in assets that operates 19 branches in 6 counties with 165 employees. Mr. Griffith is currently Chairman of the Board of Trustees of the First Church of Round Hill in Greenwich, Connecticut. A graduate of the J.L. Kellogg Graduate School of Management at Northwestern University, Mr. Griffith was an investment banker for nearly 15 years, including positions as Director of Equity Capital Markets at Credit Suisse First Boston and High Yield Capital Markets at Bankers Trust Company, both in New York.

In January 2005, the Board of Directors created an Executive Committee of the Board to consist of Drs. Marvin Hausman and Gosse Bruinsma and independent directors Dr. Ralph Snyderman and Mr. Michael A. Griffith.

On February 7, 2005, we announced that the top line outcome of our first Phase III clinical trial with Phenserine, in development for mild to moderate Alzheimer's disease (AD), showed that although there were encouraging trends with both Phenserine 10mg and 15mg twice daily, overall these did not result in a statistically significant improvement over placebo for the protocol's primary endpoints following 26 weeks of treatment. While Phenserine-treated patients performed better in the ADAS-cog and CIBIC assessments, the study's primary endpoints at almost all time points, the outcome was potentially confounded by a better than expected ADAS-cog response in the placebo-treated patients. A preliminary review of the adverse events has revealed no safety or tolerability concerns associated with Phenserine treatment. The Phase III trial recruited 384 mild to moderate Alzheimer's patients, of which 375 were randomized to receive clinical trial medication, from 16 clinical sites in Spain, United Kingdom, Croatia, and Austria. Patients, after being diagnosed as having probable AD, were randomized to receive placebo, Phenserine 10mg twice daily or 15mg twice daily for a period of 6 months. Throughout the treatment period patients were regularly assessed using standard cognition and memory assessments. We have halted additional patient recruitment for the ongoing Phase III clinical trials in order to evaluate the planned Phenserine clinical development program following recommendations from our Scientific Advisory Board and Safety Steering Committee, as well as our desire to examine opportunities that could optimize further Phenserine development.

Axonyx, Dr. M. Hausman, Dr. G. Bruinsma and Mr. S. Colin Neill have been named as defendants in several purported shareholder class action lawsuits filed in February 2005 alleging violations of federal securities laws. The lawsuits are pending in the U.S. District Court for the Southern District of New York and assert claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of our common stock during the period from June 26, 2003, through and including February 4, 2005 (the "Class Period"). The complaints allege generally that the defendants knowingly or recklessly made false or misleading statements during the Class Period regarding the effectiveness of Phenserine in treating mild to moderate Alzheimer's disease, which had the effect of artificially inflating the price of our shares. The complaints seek unspecified damages. We believe the complaints are without merit and intend to defend these lawsuits vigorously. However, we cannot assure you that we will prevail in this action, and, if the outcome is unfavorable to Axonyx, our reputation, operations and share price could be adversely affected.

On February 28, 2005 OXIS announced that Mr. Steven T. Guillen had joined OXIS as President and Chief Executive Officer and as a member of the OXIS Board of Directors. Consequently the Company no longer has a majority of the seats on the OXIS Board, and because the Company's ownership interest now represents 34%

of the OXIS shares outstanding, beginning March 1, 2005 OXIS will no longer be consolidated but rather accounted for using the equity method in the Axonyx financial statements.

On March 3, 2005 we announced that Dr. Bruinsma has succeeded Dr. Hausman as our Chief Executive Officer. Dr. Hausman will continue to serve as Chairman of the Board.

On March 11, 2005 we announced interim statistical results from the first 37 patients in a Phase IIb clinical trial designed to evaluate the effects of Phenserine tartrate on cerebrospinal fluid (CSF) concentrations of beta-Amyloid (A β 1-42) in Alzheimer's Disease (AD) patients. We scheduled this interim analysis to assess the benefit of continuing enrollment to the target of 150 patients, and the data produced was sufficient to suggest a dose response resulting in a lowering of A β 1-42 in the CSF of Alzheimer's patients. We believe that the results obtained from this interim analysis of 37 patients justifies continued enrollment to the higher of the two dose groups (15mg) in the study. Completion of patient enrollment of this trial is anticipated in the second quarter 2005 with final results in the last quarter 2005.

B. Axonyx — Introduction, Business Strategy

We are a biopharmaceutical company, specializing in central nervous system (CNS) neurodegenerative diseases, engaged in the business of acquiring the patent rights to clinical stage compounds, compounds with strong proof of concept data and compounds ready for proof of concept validation with convincing scientific rationale. We further develop and add value to these compounds and then seek to out-license or partner them when we believe it business prudent. We have acquired worldwide exclusive patent rights to three main classes of therapeutic compounds designed for the treatment of Alzheimer's disease (AD) and other memory impairments generally associated with elderly and related diseases. We have acquired patent rights to a class of potential therapeutic compounds designed for the treatment of prion related diseases, which are degenerative diseases of the brain that are thought to be caused by an infectious form of a protein called a prion. Prions, unlike viruses, bacteria and fungi, have no DNA and consist only of protein. Such diseases include Creutzfeldt Jakob Disease, new variant in humans, Bovine Spongiform Encephalopathy (BSE or Mad Cow Disease) in cows, and Scrapies disease in sheep. We have licensed these patent rights separately from New York University and from the National Institutes of Health/National Institute on Aging (via a sublicense). We also have co-inventorship rights to a patent application regarding a therapeutic compound named Posiphen potentially of value for the treatment of Alzheimer's disease.

The Company's lead drug, Phenserine, is a third generation acetylcholinesterase inhibitor, which has progressed to late stage clinical trials. As of December 31, 2004, we had expected future contractual payments to various clinical research organizations in connection with these trials aggregating \$15,801,000, including \$15,292,000 for 2005. The nature of the clinical research contracts is such that work can be stopped at short notice and the obligation would be to pay costs incurred to date. The results of the 1st Phase III trial were announced on February 7, 2005 and the interim results from the Phase IIb trial were announced on March 11, 2005 and are described under "Recent Events — Item 1 Section A." Overall the results from each trial did not show statistically significant improvements over placebo for the protocol's primary endpoints following 26 weeks of treatment. We have halted additional patient recruitment to the ongoing phase III clinical trials in order to evaluate the planned Phenserine clinical development program following recommendations from our Scientific Advisory Board and Safety Steering Committee, as well as our desire to examine opportunities that could optimize further Phenserine development.

We out-source all of our pre-clinical and clinical research and development activities, utilizing contract research organizations, or CROs, and sponsored research arrangements. We have contracted with several CROs to undertake the pre-clinical and clinical development of Phenserine and our other drug candidates. We have entered into a License Agreement with Applied Research Systems ARS Holding N.V. (ARS), a subsidiary of Serono International, S.A. (Serono), a Swiss biopharmaceutical company, under which ARS has the rights to conduct research and development on certain of our licensed technologies. We received an up-front fee and a milestone payment, and may receive future milestone payments and royalties, under the License Agreement. We are currently renegotiating our arrangement with Serono as discussed in Recent Developments above and Section G below — Strategic Alliances. We do not maintain any laboratory or research premises.

Our current business strategy is to concentrate our financial resources primarily on the further development of our licensed compounds. Phenserine, an inhibitor of acetylcholinesterase, is our lead drug candidate for the

treatment of AD. Acetylcholinesterase is an enzyme in the synapse that degrades the neurotransmitter acetylcholine in the brain and other tissues of the body. Acetylcholine is a chemical substance that sends signals between nerve cells, called neurotransmission, and is therefore called a neurotransmitter. Neurotransmitters are secreted by neurons, or nerve cells, into the space between neurons called the synapse. Acetylcholine is a primary neurotransmitter in the brain, and is associated with memory and cognition.

In early June 2003, we initiated a Phase IIb clinical trial designed to evaluate the effects of Phenserine on the levels of beta-amyloid precursor protein and beta amyloid in the plasma and cerebrospinal fluid of mild to moderate AD patients. The beta amyloid protein is one of more than a dozen types of amyloid proteins found in the body. Beta amyloid is derived from the beta-amyloid precursor protein and is normally present in the brain of healthy individuals. Beta-amyloid, derived from the beta-amyloid precursor protein, may be over-produced in AD and it undergoes a conformational change, aggregates and is deposited as insoluble fibrils in amyloid plaques in the brain. The beta-amyloid precursor protein is present in the cell wall of numerous cells within the body including nerve cells of the brain. Beta-amyloid protein is derived from this larger protein. In late June 2003 we also initiated a Phase III clinical trial to further examine the safety and efficacy of Phenserine treatment in mild to moderate AD patients. In June 2004 we completed enrollment in the 1st Phase III trial and initiated a 2nd Phase III trial with 450 patients. We initiated a third Phase III cognition trial, also with a target of 450 patients, in September 2004. The results of our 1st Phase III trial were announced on February 7, 2005, and interim results of the Phase IIb trial were announced on March 11, 2005; both announcements are described above under "Item 1 — Business — Recent Events."

Pursuant to a sublicense agreement with ARS, ARS has the rights to undertake research and development concerning the development of (1) compounds called Amyloid Inhibitory Peptides ("AIPs"), which may prevent and reverse the formation of amyloid plaques in AD, and (2) a pharmaceutical compound for prion-related diseases. In Alzheimer's disease the conversion of beta-amyloid protein into insoluble beta-amyloid sheets that aggregate to form insoluble fibrous masses (fibrils) is thought to be a key event that leads eventually to neuronal cell death in the brains of AD patients. These fibrils are deposited as part of the amyloid plaques that appear to be a cause of the death of neurons in the brain. The AIPs, also referred to as "beta-sheet breaker" peptides, have been designed to block the aggregation of beta-amyloid in a competitive manner by binding to the beta-sheet form of the amyloid protein, thus preventing the formation of amyloid plaques in the brain. The beta-sheet breaker peptide is a molecule composed of naturally occurring amino acids, the building blocks of proteins, which is designed to bind to and prevent the conversion of the normal form of protein to the misshapen form that is found in amyloid plaques.

We have initiated the development of Posiphen, a compound that appears to decrease the formation of the beta-amyloid precursor protein with potential applications in the treatment of AD, and given sufficient financial resources, we may, in the future, sponsor further pre-clinical development of Tolserine, another acetylcholinesterase inhibitor as well as one of our butyrylcholinesterase inhibitors. Acetylcholinesterase inhibitors are drugs designed to selectively inhibit acetylcholinesterase. Butyrylcholinesterase is an enzyme that is normally found widely in the body. Its function in the central nervous system remains to be fully understood. Butyrylcholinesterase is found in high concentration in the plaques taken from individuals who have died from AD.

The company's AD targeted approaches include:

- Phenserine, an inhibitor of acetylcholinesterase and the beta-amyloid precursor protein, our lead drug candidate, and Tolserine, another follow-on acetylcholinesterase inhibitor;
- a butyrylcholinesterase inhibitor which will be chosen from a series of selectively acting compounds; our lead candidate is Bisnorcymcerine from this class.
- Posiphen, a compound that decreases the formation of beta-amyloid precursor protein; and
- through our sublicense with ARS, a subsidiary of Serono, which is described in greater detail below, compounds called Amyloid Inhibitory Peptides (AIPs) which may prevent and reverse the formation of amyloid plaques in AD.

On May 2, 2000, ARS, a subsidiary of Serono, exercised its right to license certain of our patent rights under the Development Agreement and Right to License signed with us in May of 1999. Under that agreement, ARS paid us a \$250,000 non-refundable fee for the right to license. Pursuant to the resulting License Agreement, which became

effective on September 15, 2000, ARS acquired exclusive worldwide patent rights to our AIP and Prion Inhibitory Peptide technologies, called the Licensed Products. In conjunction with the signing of the License Agreement with ARS, we generated \$1.5 million of revenue in the form of an up-front license fee. We received a milestone payment of \$1 million in April 2003 from ARS in relation to the initiation of a Phase I clinical trial with a licensed AIP compound. While the License Agreement provides for additional revenues from ARS if they reach certain development milestones concerning the Licensed Products or other products and related intellectual property, we are currently in protracted discussions with Serono as discussed below under "Item 1 — Business — Strategic Alliances."

We are also funding research at Monash University in Australia relating to the development of an assay method for the rapid screening of potential drug candidates for the treatment of Alzheimer's disease. We have signed a Research Agreement with the principal researcher, David Henry Small, Ph.D., to fund this research over a three-year period ending in May 2005.

In December 2000, The Company incorporated Axonyx Europe BV, a wholly owned subsidiary, in the Netherlands. Gosse Bruinsma, M.D., currently the President and Chief Executive Officer of Axonyx Inc., is also the President of Axonyx Europe BV. The majority of our clinical development activities and a significant amount of our pre-clinical development activities are carried out in Europe. The Axonyx Europe BV office manages, directs, and controls these activities. Axonyx Europe BV explores and pursues in-licensing and out-licensing opportunities for The Company's licensed technologies in Europe and elsewhere, and facilitates communication with the Company's European shareholders and Serono.

We have incurred negative cash flows from operations since the inception of the Company in 1997. Our net losses for the three fiscal years ended 2002, 2003 and 2004 were \$6,256,000, \$8,106,000 and \$28,780,000 respectively. Except for OXIS, we have no products available for sale and we do not expect to have any products commercially available for several years, if at all.

On January 15, 2004, we entered into separate agreements with several holders of the common stock of OXIS International, Inc. (OTC: OXIS.OB) ("OXIS") to acquire, at the time, approximately 52% of the outstanding voting stock of OXIS. OXIS is a biopharmaceutical/diagnostic company engaged in the development of research diagnostics, nutraceuticals and therapeutics in the field of oxidative stress. We acquired an aggregate of approximately 14 million shares of OXIS stock, in consideration for our issuance of an aggregate of approximately 1.6 million shares of our unregistered common stock. We filed a registration statement on Form S-3 to register the shares of Axonyx common stock that were issued in the exchange, which was declared effective by the SEC in May 2004. Marvin S. Hausman, M.D., our Chairman and former Chief Executive Officer, owns 1,161,532 shares of OXIS common stock, representing at the time of the original acquisitions approximately 4% of OXIS' voting stock. Dr. Hausman's shares of OXIS common stock were not subject to this exchange for our common stock. On December 10, 2004, Dr. Hausman became acting Chief Executive Officer and acting Chief Financial Officer of OXIS. On February 28, 2005, OXIS announced the appointment of Steven T. Guillen as full-time Chief Executive Officer, replacing Dr. Hausman, who continues as Chairman of the Board and acting Chief Financial Officer. As a result of certain equity transactions by OXIS, as of December 31, 2004, our ownership was reduced to 34%.

Axonyx Inc. was incorporated in Nevada on July 29, 1997. Our principal executive offices are located at 500 Seventh Avenue, 10th Floor, New York, New York 10018, and our telephone number is (212) 645-7704.

C. Axonyx Drug Development Programs

General

We are currently focusing on the development of our lead acetylcholinesterase inhibitor, Phenserine, Posiphen and one of the butyrylcholinesterase inhibitors. In addition, we are sponsoring pre-clinical research on an assay method for screening drug candidates for Alzheimer's disease being developed at Monash University in Australia as well as basic research at the medical University of South Carolina and the University of Indiana in the area of amyloid production and metabolism.

Our most advanced compound, Phenserine, is designed to selectively inhibit acetylcholinesterase, the enzyme primarily responsible for degrading acetylcholine at the synaptic gap between neurons, thus increasing the

availability of this neurotransmitter. As shown in pre-clinical studies, Phenserine also has the ability to inhibit the formation of the beta-amyloid precursor protein (beta-APP), a large protein that when conformationally changed is the source of a neurotoxic beta amyloid peptide. By inhibiting the formation of beta-APP, Phenserine has been shown to decrease the presence of the soluble beta amyloid protein that is potentially deposited in the brain as amyloid plaques that apparently cause eventual neuronal cell death.

Posiphen is the positive isomer of Phenserine and appears to lack the same level of cholinergic activity associated with Phenserine including the common side effects of the anti-cholinesterases. Posiphen has been shown in pre-clinical studies to decrease the formation of beta amyloid precursor protein and therefore has potential applications in the treatment of Alzheimer's disease progression.

A butyrylcholinesterase inhibitor will be chosen from a series of selectively acting compounds, and it is anticipated that pre-IND development work will commence in 2005.

Through our sublicense with ARS, a subsidiary of Serono International, S.A., ARS has conducted research at Serono research and development facilities on compounds called Amyloid Inhibitory Peptides (AIPs) which may prevent and reverse the formation of amyloid plaques in AD. ARS, at Serono research and development facilities, also has the right to conduct research on compounds called Prion Inhibitory Peptides (PIPs) designed for the diagnosis and treatment of prion diseases such as Bovine Spongiform Encephalopathy (also known as Mad Cow Disease) and the human form of the disease, Creutzfeldt Jakob Disease, new variant.

Despite the fact that we cannot assure you that the technologies and pharmaceutical compounds that we are developing will ultimately prove to be profitable, we will be required to continue to spend substantial capital on research and development in the foreseeable future in order to enhance our proprietary pharmaceutical portfolio, and to seek to acquire new potential products. New technologies and/or pharmaceutical compounds in the field of AD, Mild Cognitive Impairment, related diseases associated with cognitive impairment, and prion related diseases by other entities and future marketplace conditions could adversely affect the future marketability and/or profitability of our proprietary products. Consequently, we will need to continue our funding of research and development of new technologies and pharmaceutical compounds in order to remain competitive. In fiscal years 2002, 2003 and 2004 we spent \$2,610,000, \$4,627,000 and \$20,635,000 respectively, on sponsored and contract research and development activities associated with our technologies and pharmaceutical compounds.

Alzheimer's Disease Overview

Alzheimer's disease is a degenerative brain disease that, with individual variations, advances from memory lapses to confusion, personality and behavior changes, communication problems and impaired judgment. Over time, AD patients become increasingly unable to care for themselves, and the disease eventually leads to death. It is estimated that more than 4 million Americans and 12 million people worldwide suffer from AD. Risk factors for the disease include age and family history. According to the Alzheimer's Association, the disease affects one in 10 persons over 65 and half of those over 85 years old are affected by the disease.

While scientists are not completely certain of the specific causes of Alzheimer's, scientific discoveries have identified important hallmarks of the disease. Two schools of thought in the scientific community have been historically divided between those that believe that the neurofibrillary tangles composed of tau protein within the nerve cells are responsible for the disease and those that believe that the senile plaques composed of beta-amyloid protein are the cause. Both neurofibrillary tangles within brain nerve cells and extracellular senile amyloid plaques in the cholinergic nerve pathways of the brain have been linked to the death of nerve cells in AD patients. Recent research indicates that a disruption or an abnormality in beta-amyloid metabolism and the formation of amyloid plaques are most likely to be the primary causes of AD.

According to the most widely accepted theory concerning the cause of AD, there are two important events leading to the formation of beta-amyloid plaques. The first event involves the abnormal processing of the beta-amyloid precursor protein (beta-APP). In AD, beta-APP is sequentially cleaved into pieces by two enzymes, creating protein fragments, one of which is the beta-amyloid peptide. The second key event is the conversion of beta-amyloid into insoluble beta-sheets that aggregate to form insoluble fibrous masses (fibrils). These fibrils are deposited as part of the neurotoxic amyloid plaques that appear to cause the death of neurons in the brain. The beta-amyloid

protein is a protein normally found in the brain and appears to be over-produced in AD and is considered the toxic agent responsible for neuronal cell death. There are a number of strategies for preventing the formation of these amyloid plaques: (1) preventing the formation of beta-amyloid through the inhibition of the processing of its parent molecule, beta-APP, (2) inhibiting the enzymes that cleave the beta-APP, (3) removing beta-amyloid from the brain or preventing its aggregation into plaques, and (4) the disassembly of the existing amyloid plaques.

Alzheimer's disease is characterized by increasing cognitive impairment and progressive loss of memory. These impairments are caused, over time, by a loss of neurons of the cholinergic system of the brain and a loss of cortically-projecting neurons that connect the mid-brain with the cortical areas in the forebrain, particularly affecting brain areas associated with memory and learning. The cholinergic system is also called the parasympathetic nervous system; it is involved in nerve transmission related to memory and cognition, as well as the involuntary functioning of major organs such as the heart, lungs and gastrointestinal system. Cortically-projecting neurons are the nerve cells that connect the mid-brain to the cortical areas in the front part of the brain where nerve cells involved in memory and cognition are concentrated. In AD, the loss of these connecting nerve cells results in a reduction in the amount of the neurotransmitter acetylcholine, and the loss of mental capacity or cognition. Under normal healthy conditions, the neurotransmitter acetylcholine is produced by cholinergic neurons and released to carry messages to other cells, then broken down for reuse. The production and transmission of signals across neurons by acetylcholine is responsible, at least in part, for our memory, learning and cognitive functions. Having caused a signal to be passed from one neuron to the next, acetylcholine is subsequently broken down by an enzyme called acetylcholinesterase. In AD, the loss of these cholinergic neurons results in the decreased synthesis and availability of acetylcholine. By inhibiting acetylcholinesterase, the amount of available acetylcholine to carry messages between surviving neurons is increased, leading to improvements in memory and cognition.

Recent research suggests that for specific nerve pathways within the brain of AD patients the presence of the enzyme butyrylcholinesterase increases relative to acetylcholinesterase. Normally these two enzymes coexist throughout the body, with acetylcholinesterase predominating in degrading acetylcholine. Butyrylcholinesterase is additionally found in many other body tissues and functions to degrade a number of drugs such as codeine. In the brain of AD patients, as acetylcholinesterase levels gradually fall there is a parallel increase in butyrylcholinesterase levels in specific nerve pathways within the cortex and the hippocampus, areas associated with AD. Like acetylcholinesterase, butyrylcholinesterase degrades acetylcholine at the synaptic gap between neurons, decreasing the availability of this key neurotransmitter. Research in cell culture studies indicates that the increase in butyrylcholinesterase activity amplifies the toxicity of beta amyloid. This enzyme was identified as a target for inhibition in AD as it also terminates the action of the neurotransmitter acetylcholine in specific nerve pathways in regions of the brain associated with AD and is found in high concentration in amyloid plaques in the brains of AD patients.

The treatment of people with AD is a multi billion-dollar industry in the United States alone and constitutes an extremely large and continually expanding potential market with an unmet therapeutic need. Currently there are four drugs that have been approved in the United States that provide symptomatic relief for one aspect of AD, inhibition of acetylcholinesterase: Cognex® (developed by Warner Lambert), Aricept® (Pfizer and Eisai), Exelon® (Novartis) and Reminyl® (Johnson & Johnson). One of the Axonyx compounds, Phenserine, is also an acetylcholinesterase inhibitor. Unlike the other marketed compounds Phenserine has demonstrated, in pre-clinical testing utilizing transgenic mice, the ability to inhibit the formation of beta-APP and to reduce levels of the beta-amyloid peptide, the primary component of amyloid plaques. Axonyx's butyrylcholinesterase inhibitor drug candidates attack the disease in other potentially effective ways, representing a potentially new platform technology for the treatment of AD.

Given the complexity of the disease, and uncertainty concerning the specific mechanisms causing AD, it appears likely that a multi-drug approach to treating the disease will be utilized in the future. We believe that safe and effective drugs could potentially be prescribed in order to attack the disease through a number of different mechanisms of action.

In addition to inhibiting key enzymes associated with the neural transmission of acetylcholine in pre-clinical studies conducted by the National Institutes of Aging (NIA) and other independent laboratories, the acetylcholinesterase inhibitor Phenserine, Posiphen and our butyrylcholinesterase inhibitors appear to have the ability to inhibit the formation of beta-APP and to reduce levels of the beta-amyloid peptide, the primary component of amyloid plaques.

Phenserine: An Inhibitor of Acetylcholinesterase and Beta-Amyloid Precursor Protein (Beta-APP) Formation

Our most advanced compound, Phenserine, selectively inhibits acetylcholinesterase, the enzyme primarily responsible for degrading acetylcholine at the synaptic gap between neurons, thus increasing the availability of this neurotransmitter. Phenserine has been shown to be a potent and selective inhibitor of this enzyme in the rat brain and increases memory and learning over a wide therapeutic dosage range in aged rats without causing toxic side effects. The compound readily enters the brain, has minimal activity in other organs outside the brain, and has a long duration of action. In pre-clinical studies, Phenserine was shown to have a brain to blood ratio of 10:1. Increasing the concentration of the active drug agent in the brain versus the rest of the body potentially maximizes the effects of the drug while potentially reducing peripherally mediated side effects.

Phenserine also has been shown to have the ability to inhibit the formation of the beta-amyloid precursor protein (beta-APP), a large protein that is the source of the neurotoxic peptide, beta amyloid. By inhibiting the formation of beta-APP, Phenserine can decrease the presence of the soluble beta amyloid protein that is potentially deposited in the brain as amyloid plaques, apparently causing eventual neuronal cell death. These studies were conducted at laboratories at the NIA in human neuroblastoma cell cultures and *in vivo* in rodents. Studies in human neuroblastoma cell lines showed that the compound reduces the formation of beta-amyloid peptide. Neuroblastoma cell cultures are a type of cell derived from the human brain that can be grown in containers in the lab (*in vitro*) where they are able to reproduce and carry out many activities as if they were residing in the brain, including the synthesis and secretion of proteins such as the beta-amyloid protein which, in the human brain, can form plaques. A neuroblastoma cell culture is used to study brain cell function in a simple *in vitro* system, which allows testing of the ability of drugs to prevent the formation of the beta-amyloid precursor protein and secretion of beta amyloid. Additional animal studies using the transgenic mouse have confirmed these findings. The transgenic mouse is a bio-engineered animal that mimics hallmark pathologic changes that occur in the human AD brain. These results suggest that Phenserine may have the ability to slow the progression of AD in addition to providing symptomatic relief for the cognitive changes.

In December 1999, we initiated Phase I human clinical trials for Phenserine utilizing healthy elderly patients at a U.S. research center. These Phase I safety and tolerance trials involving both single and multiple dosing were successfully completed in September 2000.

In October 2001, we completed a Phase II proof-of-concept double-blind placebo-controlled clinical trial with Phenserine in AD patients. This Phase II proof-of-concept trial was designed to determine the drug's safety and possibly a trend toward efficacy in patients exhibiting mild to moderate AD. The trial included 72 patients, with 48 patients receiving two daily doses of Phenserine 10mg and 24 patients received a placebo. The safety results from the trial substantiated Phase I results indicating that the drug is safe and well tolerated. There was a low incidence of side effects associated with the digestive tract, with 8.5% of patients receiving the drug reporting nausea and 2.1% reporting vomiting. Dizziness, reported by 17% of the patients receiving the maintenance dose of the drug, was the side effect reported most often. Although the trial was not of the duration necessary and did not include the number of patients required to detect statistically significant clinical improvement in efficacy, nevertheless certain memory tests showed statistically significant results while other tests showed a trend towards statistical significance.

We initiated two related Phenserine clinical trials in June 2003. The first is was a randomized placebo-controlled double-blind Phase IIb trial that will evaluate the effects of two different dosages of Phenserine given for a six month period on the levels of the beta-amyloid precursor protein (beta-APP) and beta amyloid in the plasma and cerebrospinal fluid of 75 mild to moderate Alzheimer's disease patients. The target enrollment was subsequently increased to 150 patients. This Phase IIb trial is intended to substantiate *in vitro* and *in vivo* pre-clinical data that has consistently shown that Phenserine can reduce the levels of beta-APP and beta amyloid, and could therefore potentially differentiate Phenserine from the acetylcholinesterase inhibitors currently on the market. It is believed by many that one of the key underlying pathological processes in Alzheimer's disease is associated with the amyloid cascade and inhibition of this process could potentially modify Alzheimer's disease progression. Patients in this trial also undergo testing with the standard memory and cognition tests recommended by the United States FDA and European regulatory authorities. This Phase IIb trial is underway at several facilities in Europe. On March 11 we announced the results of an interim statistical analysis, please see "Recent Events" above. We have contracted

with JSW Research, an Austrian contract research organization to undertake this trial. Other CROs provide program management, program quality assurance, manage and analyze the data associated with this clinical trial.

Based on the encouraging Phase II clinical results, we determined that a Phase III clinical trial was warranted. In preparation for Phase III clinical trials, we completed a number of pre-clinical tests on the final drug formulation of Phenserine, scaled up of production of the final formulation to meet NDA manufacturing and potential future commercialization requirements, advanced drug stability studies, and designed the protocol for the Phase III clinical trial. The clinical protocol was submitted to the relevant national Regulatory Authorities in Europe and was included with U.S. FDA Annual Phenserine IND update. We contracted with contracting research organizations to complete this work. NOTOX Safety and Environmental Research B.V. of Holland has been awarded an approximately \$1.4 million contract to conduct a pre-clinical carcinogenicity study, that began in October 2002, and is expected to be reported in the second quarter of 2005. Other CROs conducted Phase I clinical bioavailability trials and shelf life testing on the final formulation of Phenserine. During 2002, Rhodia Pharma Solutions, an active pharmaceutical ingredient (API) manufacturer, was engaged to develop and manufacture Phenserine drug product at scale.

Following these preparations, a second trial was initiated in June 2003 and was designed to potentially be one of the pivotal Phase III trials for the NDA submission in the USA and its equivalent in Europe. The results of this 1st Phase III trial were announced on February 7, 2005 and are described in Section A under "Recent Events." This randomized double-blind placebo-controlled trial was conducted at multiple centers throughout Europe. It examined the safety and efficacy of two dosages of Phenserine given for a six-month period in mild to moderate Alzheimer's disease patients. The ability of Phenserine to improve memory and cognition was measured by the standard ADAS-cog and CIBIC-plus efficacy endpoints, which are recommended by the FDA as well as the ADCS-ADL to meet European regulatory requirements. This Phase III trial recruited 384 patients of which 375 patients were randomized and received clinical trial medication, and was contracted to JSW Research, which undertook the running of this clinical trial for us, with other CROs providing the program management and program quality assurance and data management and analysis with regard to the clinical trial.

The results of the first Phase III trial and interim results from the Phase IIb trial were announced on February 7, 2005 and March 11, 2005, respectively, and are described above under "Recent Events" in Item 1 Section A.

In June and September 2004, we initiated our 2nd and 3rd Phase III trials, respectively, each with a targeted enrollment of 450 mild to moderate AD patients. Each of these trials is a double blind placebo controlled, with a randomization of one third each in the 10mg and 15mg twice daily and placebo groups. Both of these clinical trials are contracted to, and conducted by, the CRO PPD Global Ltd. On March 11, 2005, we announced that we have halted additional patient enrollment in these trials as discussed above under "Recent Events."

Sponsored Research Program: Alzheimer's Disease Assay Method Development Program

Effective September 1, 2002, we entered into a Research Agreement and a Consulting Agreement with David Henry Small, Ph.D., and an Intellectual Property Assignment Agreement with David Henry Small, Ph.D., Marie-Isabel Aquilar, Ph.D., Supundi Subasinghe ("Assignment Agreement"). Each of these agreements relate to the development of an assay method for the rapid screening of potential drug candidates for the treatment of Alzheimer's Disease. The Research Agreement funds a research project concerning further development of the assay method under the guidance of Dr. Small for a three year period commencing October 1, 2002, for Australian \$90,000 per year. The research project pursuant to the Research Agreement is being undertaken by Dr. Small at Monash University in Clayton, Australia.

Under the Assignment Agreement Dr. Small and two other co-inventors have assigned a patent application concerning the assay method in return for revenue sharing upon commercialization of the assay method. Under the Consulting Agreement with Dr. Small, we engaged Dr. Small for a three year period for Australian \$20,000 per year and a grant of stock options for consulting services related to the development of the assay method.

The assay method that is the subject of the patent application and the sponsored research project is a process targeted at identifying early biochemical events associated with beta-amyloid toxicity. The accumulation of beta-amyloid in the brain is one of the key biochemical events in Alzheimer's disease. Dr. Small's research with this process confirmed the central role of beta-amyloid binding as a key pathological event in nerve cell membrane

damage. Data from pre-clinical *in vitro* studies undertaken in Dr. Small's laboratory has shown that there is a strong correlation between the binding of beta-amyloid to cell membranes and the resulting cell damage. The assay method process is based on a technique known as "surface plasmon resonance". The assay method can be used to further the discovery of potential Alzheimer's disease drug candidates that have a specific action on the damage caused by beta-amyloid.

Other Compounds in the Axonyx Drug Portfolio

There are other potential pharmaceutical compounds that we have patents rights to that may be further developed in the future, given sufficient financial resources.

Other Acetylcholinesterase Inhibitors

We have assessed certain properties of our other inhibitors of acetylcholinesterase such as Tolserine, that may ultimately prove to have certain additional advantages for use in AD, and Thiatolserine, a compound that has characteristics that may be suitable for development as a transdermal agent, one that is absorbed through a patch placed on the skin.

Inhibitors of Butyrylcholinesterase and Beta-Amyloid Precursor Protein (Beta-APP) Formation

Our butyrylcholinesterase inhibitor compounds are designed to selectively inhibit butyrylcholinesterase, an enzyme similar to acetylcholinesterase. Normally these two enzymes coexist throughout the body, with acetylcholinesterase predominating in degrading acetylcholine. In the brain of AD patients, as acetylcholinesterase levels gradually fall, there appears to be a concomitant increase in butyrylcholinesterase levels in specific nerve pathways within the cortex and the hippocampus, areas associated with AD. Like acetylcholinesterase, butyrylcholinesterase degrades acetylcholine at the synaptic gap between neurons, decreasing the availability of this key neurotransmitter. This enzyme was identified as a target for inhibition in AD as it also terminates the action of the neurotransmitter acetylcholine in specific nerve pathways in regions of the brain associated with AD and is found in high concentration in amyloid plaques in the brains of AD patients. Our butyrylcholinesterase inhibitor compounds act to counter butyrylcholinesterase, thus enhancing the availability of acetylcholine, improving memory and cognition. Inhibition of butyrylcholinesterase may also reduce any increased toxicity of beta amyloid caused by the presence of butyrylcholinesterase in amyloid plaques.

Several of the butyrylcholinesterase inhibitor drug candidates in our drug portfolio, including Cymserine, Phenethylnorcymserine (PENC) and Bisnorcymserine, have been studied extensively in pre-clinical studies and have been found to have many of the characteristics desirable for use in AD. Like Phenserine, these compounds have a dual mechanism of action in that, in addition to inhibiting the butyrylcholinesterase enzyme, they also inhibit the formation of beta-APP in cell culture, and in rats. These pre-clinical findings indicate that these butyrylcholinesterase inhibitor compounds may have an important role in preventing the formation of amyloid plaques in AD, in addition to its inhibition of butyrylcholinesterase. The compounds readily enter the brain, they have a long duration of action and are highly active in improving memory and learning in the aged rat. Currently it appears that Bisnorcymserine has several advantages over the other compounds in pre-clinical results. Bisnorcymserine appears to be the most potent butyrylcholinesterase inhibitor in our patent portfolio, has a 100-fold selectivity over acetylcholinesterase, behavioral work shows it to improve memory in rodent models, and it reduces beta-APP in tissue cultures. Bisnorcymserine has three potential uses: (1) as an inhibitor of butyrylcholinesterase, (2) as an inhibitor of the production of beta-APP, thus inhibiting the formation of amyloid plaques, and (3) as an early diagnostic marker. Using PENC, we have successfully developed a manufacturing process that could serve as a model for the scale up process to produce sufficient quantities of Bisnorcymserine for further studies.

Posiphen™

On March 22, 2002, we filed a provisional patent application resulting from a collaboration between Gosse B. Bruinsma, M.D. of Axonyx and Dr. Nigel Greig of the NIH/NIA, on a co-inventorship basis, covering a method for treating patients with Alzheimer's disease and other cognitive disorders with Posiphen™, a potential pharmaceutical compound that is the positive isomer of Phenserine. An International PCT application claiming the benefit of the provisional patent application was filed on March 18, 2003, and has entered the national phase in

a number of countries, including, among others, the U.S., Japan, and the regional European Patent Office. PosiphenTM, unlike Phenserine, appears to lack the same level of acetylcholinesterase inhibition activity. PosiphenTM's mechanism of action results in decreases in the formation of the beta-amyloid precursor protein through RNA translational inhibition. Axonyx owns this patent application jointly with the NIH/NIA. Initial manufacture of small quantities of PosiphenTM has been successful and these will be used for the preclinical testing of PosiphenTM. This preclinical testing may potentially support future clinical trials in human subjects. Human studies will require approval from regulatory agencies in the U.S. and elsewhere.

D. Out-Licensed Technology

We signed a License Agreement with Applied Research Systems ARS Holding N.V. (ARS), a wholly owned subsidiary of Serono International, S.A. (Serono) effective September 15, 2000. Serono is a Swiss-based biotechnology company listed on the NYSE. Under the License Agreement, we granted an exclusive, worldwide sublicense of our patent rights and know-how regarding the development and marketing of the Amyloid Inhibitory Peptide (AIP's) and the Prion Inhibitory Peptide (PIP's) technology, the licensed products, to ARS. The License Agreement provides for the making of milestone payments upon the occurrence of certain events in the development of the Licensed Products and royalty payments upon the sale of products resulting from the licensed technology. In addition, ARS paid us a nonrefundable and noncreditable up-front license fee in the amount of \$1.5 million. Under the License Agreement, ARS would pay us an aggregate amount of \$14 million if the licensed product involved is a patented product covered by the sub-licensed patents and patent applications achieve health registration approval. The amount of aggregate milestone payments through health registration approval would be \$7 million if the licensed product involved was developed by Serono during the term of our Development Agreement with ARS.

When we learned in 2004 that Serono was evaluating whether to continue further development of the licensed technologies, discussions were initiated with Serono to investigate whether a collaborative arrangement could be negotiated whereby Axonyx would regain control over the development activities surrounding the AIP's and PIP's. These discussions resulted in the signing of a non-binding MOU with Serono in July of 2004. (Please see Recent Events, Section A.) Any final decision to delay or terminate development on the part of Serono would mean that our receipt of any further milestone and royalty payments referred to above would in turn either be delayed or eliminated. During the first part of 2004 we were in discussions with Serono about the existing licensing arrangements and about possible alternative structures and collaborations that might be used to potentially exploit the licensed technology. As a result of these discussions, we entered into a non-binding Memorandum of Understanding with Serono regarding possible research and joint development of certain technologies, including the licensed technologies, as discussed under "Item 1 — Business — Strategic Alliances, Section G."

Amyloid Inhibitory Peptides (AIPs)

In Alzheimer's disease the conversion of beta-amyloid protein into insoluble beta-sheets that aggregate to form insoluble fibrous masses (fibrils) is a key event that leads eventually to neuronal cell death in the brains of AD patients. These fibrils are deposited as part of the neurotoxic amyloid plaques that appear to cause the death of neurons in the brain. The beta-amyloid protein is a protein normally found in the brain that is over-produced in Alzheimer's disease.

The AIPs, also referred to as beta-sheet breaker peptides, have been designed to block the aggregation of beta-amyloid in a competitive manner by binding to the beta-sheet form of the amyloid protein, thus preventing the formation of amyloid plaques in the brain. The beta-sheet breaker peptide is a molecule composed of naturally occurring amino acids, the building blocks of proteins, which is designed to bind to and prevent the conversion of the normal form of protein to the misshapen form that forms plaques.

In experiments *in vitro* and *in vivo* at labs at NYU with one of the AIPs, the compound inhibited the formation of amyloid fibrils, caused disassembly of preformed fibrils and prevented neuronal cell death in cell culture. In a rat model of amyloidosis, an AIP reduced beta-amyloid protein deposition and significantly blocked the formation of amyloid fibrils. In addition, one of the AIPs has been shown to cause a significant reduction of established amyloid deposits in the brains of rats. These results indicate the potential for a drug based on the AIP technology to prevent

the formation of the amyloid plaques, and to treat AD patients who already have amyloid plaques. Thus, the AIPs may not only prevent the formation of amyloid plaques in but also disassemble existing amyloid plaques.

Under the terms of the agreement, development of compounds based on the AIPs has been undertaken by ARS, through Serono, at the Serono Pharmaceutical Research Institute in Geneva, Switzerland. Scientists at Serono developed a formulation of the AIP compound has completed a Phase I clinical trial.

Prion Inhibitory Peptides (PIPs)

There is increasing evidence that prions are the infectious agents that cause Bovine Spongiform Encephalopathy (BSE), Creutzfeldt-Jakob Disease, new variant (nvCJD) and possibly other prion-related diseases. These diseases have caused grave concern in Europe and the U.S. because of the potential for their transmission to humans through the meat supply. These fatal neurodegenerative disorders are characterized by spongiform degeneration of the brain and, in many cases, by deposits of prions into plaques. The infectivity of prions is believed to be associated with an abnormal folding of the prion protein. This folding involves a conversion of the alpha-helical form to the beta-sheet form that can be deposited in plaques in the brain.

ARS, through its sublicense with Axonyx, has the right to develop, at Serono facilities, a series of Prion Inhibitory Peptides, or PIPs, that interact *in vitro* with the normal form of the prion to prevent its conversion to the abnormal form, and to interact with the abnormal form to cause it to revert to a normal prion. In earlier research at NYU, incubation of the PIPs with toxic prions taken from BSE and nvCJD infected cows caused a reversion of the toxic prions to the normal form. These findings suggest a strategy for designing diagnostics and therapeutic treatments for prion related diseases.

Under the terms of our licensing agreement development of compounds based on the PIPs has been undertaken by ARS, through Serono, at the Serono Pharmaceutical Research Institute in Geneva, Switzerland.

E. Competition

We compete with many large and small pharmaceutical companies that are developing and/or marketing drug compounds similar to those being developed by us, especially in the area of acetylcholinesterase inhibitors and the amyloid cascade. Many large pharmaceutical companies and smaller biotechnology companies have well funded research departments concentrating on therapeutic approaches to AD. We expect substantial competition from these companies as they develop different and/or novel approaches to the treatment of AD. Some of these approaches may directly compete with the compounds that we are currently or are considering developing.

In the intense competitive environment that is the pharmaceutical industry, those companies that complete clinical trials, obtain regulatory approval and commercialize their drug products first will enjoy competitive advantages. We believe that the compounds covered by our patent rights have characteristics that may enable them, if fully developed, to have a market impact.

A number of major pharmaceutical companies have programs to develop drugs for the treatment of Alzheimer's disease. Like Phenserine, many of these drugs are acetylcholinesterase inhibitors. Warner-Lambert (Cognex®), Eisai/Pfizer (Aricept®), Novartis (Exelon®) and, most recently, Johnson & Johnson (Reminyl®), have marketed compounds of this type in the United States. Cognex® was effectively removed from the market in 1998 due to severe side effects and Aricept (donepezil) currently dominates the market with approximately \$1 billion in U.S. sales in 2003. Several other pharmaceutical companies have acetylcholinesterase inhibitors in human clinical trials. In addition, Forest Laboratories' Namenda™ (memantine HCl) was recently approved in the USA for the treatment of moderate to severe AD as monotherapy or in combination with donepezil, a commonly prescribed acetylcholinesterase inhibitor. Memantine has a different mechanism of action that is focused on the glutamate pathway and can potentially also be prescribed together with Phenserine and our other drug candidates in development.

Two biotechnology companies have drugs in clinical trials that are based on a beta-amyloid approach to the treatment of AD. In addition, two small biotechnology companies appear to be pursuing studies on the amyloid inhibitory peptide approach similar in scope and direction as that of our sub-licensee Serono. Another company is developing ways to inhibit plaque deposition by interfering with the transporter molecules that carry beta-amyloid from the cell membrane, where it is produced from APP, to the cell exterior where the amyloid plaques are formed.

Several pharmaceutical companies are working on compounds designed to block the secretase enzymes involved in beta-APP processing. Elan Pharmaceuticals, the California based subsidiary of the Elan Corporation of Dublin, Ireland, continues research and development work on a vaccine designed to cause the immune system to mount antibodies against the amyloid proteins that make up amyloid plaques. This work is in conjunction with Wyeth. This vaccine showed efficacy in genetically altered mice but Phase II human clinical trials were suspended by Elan due to the incidence of side effects in some patients.

In the area of butyrylcholinesterase inhibition, Novartis' drug Exelon® is a dual inhibitor of both acetylcholinesterase and butyrylcholinesterase.

Many other pharmaceutical companies are developing pharmaceutical compounds for the treatment of AD or other memory or cognition impairments based on other therapeutic approaches to the disease. These drugs could become competitors for, or have additive, synergistic clinical effects with one or more of our AD targeted drug candidates. Examples of those competitive approaches include pharmaceutical compounds designed to stimulate glutamate receptors involved in memory and learning, target nicotinic and muscarinic receptors to increase the release of certain neurotransmitters, activate nerve regeneration, magnify the signals reaching aging neurons from other brain cells, and to modulate GABA (a neurotransmitter) receptors.

In the field of prions, and prion-related diseases, one company, Prionics, A.G., of Zurich, Switzerland, has a diagnostic test for animal use that is approved in Europe. Prionics is also researching the treatment of nvCJD in humans. Two other companies have veterinary diagnostic tests for Bovine Spongiform Encephalopathy (BSE) approved in the European Union and two additional companies are developing such diagnostic tests.

F. Government Regulation

Regulation by governmental authorities in the United States and foreign countries is an important factor in the development, manufacture and marketing of our proposed products. It is expected that all of our products will require regulatory approval by governmental agencies prior to their commercialization. Human therapeutic products are subject to rigorous pre-clinical and clinical testing and other approval procedures by the Food and Drug Administration (FDA) and similar regulatory agencies in foreign countries.

Pre-clinical testing is conducted on animals in the laboratory to evaluate the potential efficacy and the safety of a potential pharmaceutical product. The results of these studies are submitted to the FDA as a part of an Investigational New Drug (IND) application, which must be approved before clinical testing in humans can begin in the USA. Typically, the clinical evaluation process involves three phases. In Phase I, clinical trials are conducted with a small number of healthy human subjects to determine the early safety profile, the pattern of drug distribution and metabolism. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease to determine preliminary evidence of efficacy, the optimal dosages, and more extensive evidence of safety. In Phase III, large scale, statistically-driven multi-center, comparative clinical trials are conducted with patients afflicted with a target disease in order to provide enough data to demonstrate the efficacy and safety required by the FDA.

The FDA requires that all pre-clinical and clinical testing, as well as manufacturing of drug product, meet certain Good Practices guidelines, including Good Manufacturing Processes, Good Laboratory Practices and Good Clinical Practices. These guidelines are designed to ensure formal training, standard operating procedures, independent performance checks and measures, the accuracy, consistency, validity and completeness of the particular activity. In our case, Contract Research Organizations, or CROs, and academic or other sponsored research laboratories that we utilize for our pre-clinical and clinical research, as well as active pharmaceutical ingredient (API) manufacturing of pure drug product, must comply with these guidelines. Our contracted manufacturers, sponsored research labs and CROs undertake to adhere to Good Manufacturing Processes, Good Laboratory Practices and Good Clinical Practices. We select only CROs that have a record of adherence to those standards and have internal quality assurance and control functions in place to ensure such adherence. However, no assurance can be given that these CROs will in fact completely adhere to the relevant standards in their work for us.

The results of all of the pre-clinical and clinical testing are submitted to the FDA in the form of a New Drug Application (NDA) for approval to commence commercial sales. In responding to an NDA, the FDA may grant

marketing approval, request additional information, or deny the application if the FDA determines that the application does not satisfy its regulatory approval criteria. We cannot assure you that approvals will be granted on a timely basis, if at all. Similar regulatory procedures are in place in most developed countries outside the United States.

In October 2001, we completed a Phase II proof of concept human clinical trial with Phenserine utilizing AD patients at five sites in the United States. The only drug for which we have filed an IND is Phenserine. Our butyrylcholinesterase inhibitor program is in pre-clinical development. The AIP product development is under the direction of Serono, through our arrangements with their subsidiary ARS, and they completed a Phase I clinical trial in 2003.

G. Strategic Alliances

New York University

On April 1, 1997 we entered into a Research and License Agreement with New York University pursuant to which NYU granted us an exclusive worldwide license to certain patent applications covering AIPs, PIPs and related technology, and any inventions that arose out of the research project funded by us. Aggregate milestone payments under the agreement total \$525,000, with \$175,000 payable once for each of one Alzheimer's disease treatment product, one prion treatment product and one neuro-imaging product. We must pay minimum annual royalty payments to NYU in the amount of \$150,000 per year beginning in 2004, through the expiration or termination of the agreement. We also undertook to comply with a development plan annexed to the agreement, that contains deadlines by which we or our sublicensee is to achieve certain development milestones, including commencing clinical trials, for an AIP and PIP compound.

Under the Research and License Agreement, we are obligated to pay all patent filing, prosecution and maintenance costs. In addition, we paid NYU \$25,000 upon signing the agreement in connection with patent expenses incurred prior to the signing of the agreement. We have the right to bring suit against any third party infringers and are responsible for all of our costs and expenses or those of NYU incurred in conjunction with such suit. If we are rewarded a recovery in our suit against a third party infringer, we may utilize such recovery to pay for our costs and expenses in bringing such action, and we must pay NYU a portion of any excess recovery over such costs and expenses. If we choose not to bring such a suit, and NYU exercises its right to do so, NYU will pay the costs and expenses of such a suit against a third party infringer. NYU has the right to reimburse itself for costs and expenses incurred in such a suit out of any sums recovered, and will pay us fifty percent of the amount of such recovery in excess of NYU's costs and expenses.

We issued an aggregate of 600,000 shares of common stock to NYU and two scientists involved in the research upon signing of the agreement. These 600,000 shares of common stock had a fair market value of \$240,000 when they were issued. In addition, we granted additional shares of common stock to NYU and the two scientists pursuant to certain anti-dilution relative to the shares issuance at a price of \$0.001 per share. We issued an aggregate of 317,369 shares of common stock to NYU and the two scientists in 2000. We recorded accounting charges of \$1,965,000 for the fair market value of 305,074 of the 317,369 shares deemed issued in 1999 and recorded accounting charges of \$138,000 for the fair market value of final tranche of 12,295 shares issued in 2000 to complete the shares issuances to NYU and the two scientists.

In addition to royalties on future sales of products developed from the patented technologies, milestone payments and patent filing and prosecution costs, we undertook to fund four years of research at the NYU School of Medicine at Dr. Frangione's laboratory at a cost of \$300,000 per year. That obligation ceased in the Fall of 2001, after we had paid an aggregate of \$1,200,000. Under the agreement with NYU, we received an exclusive license to all inventions in the field arising from this research on the AIPs and PIPs. We did not receive notice from NYU that any inventions in the field arose out of the research project on the AIPs and PIPs.

The patent license terminates, on a country-by-country basis, upon expiration of the last to expire of the licensed patents (June 2015 for the United States) or eight years from the date of first commercial sale of a licensed product in such country, whichever is later. Either party can terminate the Research and License Agreement if the other party materially breaches or defaults in the performance or observance of any of the provisions of the agreement

and such breach or default is not cured within 60 days or, in the case of failure to pay any amounts due under the agreement, within 30 days after giving notice by the other party specifying such breach or default, or automatically and without further action if either NYU or Axonyx discontinues its business or becomes insolvent or bankrupt. Upon termination of the agreement all rights in and to the covered patent rights shall revert to NYU and we will not be entitled to impinge on such patent rights. Termination of the agreement would not relieve either party of any obligation to the other party incurred prior to such termination. Certain provisions of the Research and License Agreement will survive and remain in full force and effect after any termination, including provisions relating to confidentiality, liability and indemnification, security for indemnification, and use of name of the other party without prior written consent except under certain circumstances.

On October 11, 2002, we signed a Fourth Amendment with New York University to the Research and License Agreement between New York University and Axonyx dated April 1, 1997. The amendment modifies the development plan annexed to the Research and License Agreement regarding deadlines by which Axonyx or our sublicensee is to achieve certain development milestones, including commencing clinical trials, for an AIP compound. The amendment extends the dates by which we or our sublicensee undertakes to meet certain development and commercialization benchmarks, including the commencement of Phase I clinical trials for an AIP compound. The amendment also modifies the terms of the milestone payment provisions of the Research and License Agreement, delays the due date for the next development plan report and contains releases and waivers of default by the university and Axonyx. NYU waived any past failures on our part to develop Licensed Products in accordance with the schedule provided in the development plan under the Research and License Agreement. ARS, a wholly owned subsidiary of Serono International, S.A., who sublicensed the patents covered by the Research and License Agreement between New York University and Axonyx, has been undertaking the development and commercialization of the AIP and PIP compounds at Serono facilities in Geneva, Switzerland.

CURE, LLC, Public Health Service/National Institutes of Health

On February 27, 1997, we acquired the worldwide exclusive patent rights to Phenserine, Cymserine (a butyrylcholinesterase inhibitor), their analogs (one of a series of chemical substances of similar chemical structure) and related acetylcholinesterase and butyrylcholinesterase inhibitory compounds (not including PENC or Bisnorcymserine) via a sublicense with CURE, LLC, from the Public Health Service, parent agency of the National Institutes of Health\National Institute on Aging (NIH\NIA). We have periodically sponsored some of the researchers at the NIA facilities involved in fields of research related to the licensed patent rights.

Under the license agreement, we agreed to pay royalties to CURE, LLC of up to 3% of the first \$100 million and 1% thereafter, of net product sales of, and sub-licensed royalties on, products developed from the patented technologies. We also agreed to pay an upfront fee in the amount of \$25,000, milestone payments aggregating \$600,000 when certain clinical and regulatory milestones are reached, and patent filing and prosecution costs. We have been paying minimum annual royalty payments of \$10,000 since January 31, 2000, which will increase to \$25,000 per year on commencement of sales of the product until the expiration or termination of the agreement. Any royalty payments made to CURE shall be credited against the minimum payments. Four patents have been issued in the United States.

Certain pass through provisions from the License Agreement between CURE, LLC and the PHS are contained in our License Agreement with CURE, LLC and are binding on us as if we were a party to the License Agreement with the PHS. Those provisions cover certain reserved government rights to the licensed patents, preparation, filing, maintenance and prosecution of the licensed patents, obligations to meet certain benchmarks and perform a commercial development plan, manufacturing restrictions, as well as indemnification, termination and modification of rights. PHS reserves on behalf of the U.S. government or any foreign government or international organization pursuant to any existing or future treaty or agreement with the U.S. government an irrevocable, nonexclusive, nontransferable, royalty free license for the practice of all inventions licensed pursuant to the License Agreement between CURE and PHS for research or other purposes. Prior to the first commercial sale we must provide PHS with licensed products or material for PHS' use. After making the first commercial sale of licensed products until expiration of the agreement, we must use our reasonable best efforts to make the licensed products and processes reasonably accessible to the U.S. public. PHS reserves the right to terminate or modify the License Agreement if it is determined that such action is necessary to meet requirements for public use specified by federal regulations.

We are also obligated, under these pass through provisions, to manufacture licensed products substantially in the U.S., unless a written waiver is obtained in advance from the PHS. We undertake to develop and commercialize any licensed products covered by the patents pursuant to a commercial development plan contained in a pass through provision from the CURE-PHS license agreement. If we fail to cure non-compliance with the commercial development plan after notice from CURE within a reasonable period of time, we could be in material breach of the agreement.

Under the pass through provisions from the License Agreement between CURE, LLC and the PHS, the PHS is primarily responsible for the preparation, filing, prosecution and maintenance of the patents covered by the License Agreement. Pursuant to our agreement with CURE, LLC, we have assumed full responsibility for the preparation, filing, prosecution and maintenance of the covered patents, and have reimbursed CURE, LLC for its patent expenses as part of the \$25,000 up front fee. We have the right to pursue any actions against third parties for infringement of the patents covered by our License Agreement with CURE, LLC. Upon the conclusion of any such infringement action we may bring, we are entitled to offset unrecovered litigation expenses incurred in connection with the infringement action against a percentage of the aggregate milestone payments and royalties owed to CURE, LLC. In the event that fifty percent of such litigation expenses exceed the amount of royalties payable by us, the expenses in excess may be carried over as a credit on the same basis into succeeding years. A credit against litigation expenses will not reduce the royalties due in any calendar year to less than the minimum annual royalty. Any recovery we make in such an infringement action shall be first applied to reimburse CURE for royalties withheld as a credit against litigation expenses and we may utilize the remainder to pay for our litigation expense. Any remaining recoveries will be shared equally by us and CURE.

The reversionary rights provision of the License Agreement sets certain deadlines by which we are to achieve certain development milestones, including commencing clinical trials, for Phenserine. If we fail to comply with the development benchmarks set forth in the reversionary rights provision, or the commercial development plan, or pay the required penalty fees, then all rights to the patents may, at CURE's election, revert to CURE, and the agreement will terminate. In addition, we have the right to terminate the agreement with 60 days notice without cause. Either party may terminate the agreement upon cause, if the other party materially breaches or defaults in the performance of any provision of the agreement and has not cured such breach or default within 90 days after notice of such breach or default, or if either party discontinues its business or becomes insolvent or bankrupt. Unless terminated first, the license terminates upon the last to expire of the licensed patents (December 2016 in the United States for the covered patent which will expire last).

On May 27, 2002, we signed an amendment letter with CURE, LLC that amends the License Agreement between Axonyx and CURE dated February 27, 1997. The amendment modifies the reversionary rights provision of the License Agreement regarding deadlines by which we are to achieve certain development milestones, including commencing clinical trials, for Phenserine. The amendment extends the dates by which reversionary rights arise if we fail to meet certain development benchmarks, including the commencement of Phase III clinical trials for Phenserine. On July 11, 2002, the Public Health Service, the parent agency of the NIH/NIA, signed an amendment to the Patent License Agreement — Exclusive between the Public Health Service and CURE dated January 31, 1997, which, among other things, amends the commercial development plan and benchmark provisions of the original agreement and extends the dates by which CURE or its sublicensee Axonyx is required to commence clinical trials for Phenserine and file a New Drug Application for Phenserine.

Applied Research Systems ARS Holding N.V./Sero International S.A.

Effective September 15, 2000 we entered into a License Agreement with Applied Research Systems ARS Holding N.V., a wholly owned subsidiary of Sero International S.A., covering the amyloid and prion inhibitory peptide technologies. Under this agreement we received a \$1.5 million up front payment, may receive milestone payments and royalties on the sale of approved drug compounds derived and from the licensed technology. Previously, on May 17, 1999 we and ARS had signed a Development Agreement and Right to License (Development Agreement). Under the Development Agreement, we granted an exclusive right to license the patent rights and know-how regarding the AIPs to ARS. ARS paid us a \$250,000 fee for the right to license.

Under the License Agreement with ARS, we could receive milestone payments from ARS in an aggregate amount of \$14 million if the Licensed Product involved is a patented product covered by the sub-licensed patents

and the patent application achieves certain developmental milestones up through health registration approval. The amount of aggregate milestone payments through health registration approval would be \$7 million if the licensed product involved was developed by Serono during the term of our Development Agreement with ARS.

ARS' obligation to pay royalties under the License Agreement with respect to any country extends from the date of first commercial sale in such country to the later of the tenth anniversary of the date of such first commercial sale in such country or the date of expiration or invalidation of the covered patents claiming the relevant licensed product in such country (currently June 2015 based on covered issued patents in the United States). ARS has the unilateral right to terminate the License Agreement without cause at any time upon 30 days notice to Axonyx. The agreement may be terminated for cause if the other party is in breach of its material obligations and has not cured such breach within 90 days after receipt of notice from the non-breaching party.

During 2004 we entered into discussions with Serono to alter the agreement as described above.

In July 2004, we signed a non-binding Memorandum of Understanding (MOU) for the research and joint development of therapeutic compounds including the Amyloid Inhibitory and Prion Inhibitory Peptides, and diagnostic technologies in the field of protein mis-folding disorders such as Parkinson's Disease, Down's Syndrome, Diabetic disorders, Lou Gehrig's Disease, Alzheimer's Disease, Transmissible Spongiform Encephalopathies (TSE's) i.e. Mad Cow Disease (BSE) and Creutzfeldt Jakob Disease new variant (CJDnv).

The MOU proposes that Serono and Axonyx each will transfer certain technologies and proprietary rights to a public entity they will jointly acquire, including technologies previously licensed by Axonyx to Serono, as well as additional related intellectual property and expertise subsequently developed by Serono. In addition to contributing specifically enumerated technologies to the new venture, the MOU contemplates that Axonyx will invest \$5 million. The new venture would then separately raise additional capital in the public markets to fund its research and development activities.

Under the terms of the MOU, Axonyx will have a majority of the voting stock of the new venture and initially will designate a majority of its directors.

Serono will have the exclusive option to license key technologies that have successfully completed Phase II clinical trials, in which case milestone payments and royalties would be payable to the new venture by Serono based on the attainment of certain milestones and commercialization. If Serono does not exercise such option for a particular drug compound, upon successful commercialization of the drug compound, the new venture would pay royalties to Serono.

The execution of the MOU by the parties is a result of previously disclosed discussions about alternative structures and collaborations to current licensing arrangements covering the amyloid and prion inhibitory peptide technologies.

Following the signing of the MOU, the parties have been negotiating the terms of definitive agreements. If the agreements contemplated under the MOU are finalized, the revenues and milestone payments described in earlier SEC filings under the original licensing agreements to SERONO will not occur. We cannot be assured at this time that the due diligence and/or these discussions will result in a mutually satisfactory outcome.

Dr. David Henry Small/Monash University

Effective September 1, 2002, we entered into a Research Agreement and a Consulting Agreement with David Henry Small, Ph.D., and an Intellectual Property Assignment Agreement with David Henry Small, Ph.D., Marie-Isabel Aquilar, Ph.D., Supundi Subasinghe ("Assignment Agreement"). Each of these agreements relate to the development of an assay method for the rapid screening of potential drug candidates for the treatment of Alzheimer's disease. We are responsible for patent filing and prosecution and maintenance of all patents covered by or arising from any of these agreements. The research project pursuant to the Research Agreement is being undertaken by Dr. Small at Monash University in Clayton, Australia.

The Research Agreement funds a research project concerning further development of the assay method under the guidance of the supervisor, Dr. Small, for a three year period commencing October 1, 2002 and expiring on October 1, 2005, for Australian \$90,000 per year. Dr. Small assigned all rights, title and interest in the intellectual

property arising from the research project in return for revenue sharing of future sales of net sales of products arising from the research project intellectual property. Dr. Small retained rights to all intellectual property that was the property of, claimed by, or licensed to Dr. Small prior to the effective date of the Research Agreement, or which is developed by or on behalf of Dr. Small independently of the research project during the term of the Research Agreement or of the Consulting Agreement. We granted to Dr. Small a non-exclusive, personal, non-sublicensable, non-transferable, royalty-free, worldwide, perpetual and irrevocable license to use for his own research and educational purposes the research project intellectual property. Dr. Small granted us a royalty-free, perpetual, irrevocable, non-exclusive right to the intellectual property he retains rights to the extent that it is necessary to carry out the research project or exploit the results of the research project. We have the right to terminate without cause the Research Agreement upon 90 days notice prior to the end of each anniversary of the effective date, September 1, 2002. We may also immediately terminate the agreement without cause if, in our reasonable discretion, we determine that any intellectual property being developed under the agreement infringes another party's rights. Either party may terminate the Research Agreement upon cause upon 30 days notice if the cause is not cured.

Under the Assignment Agreement Dr. Small and two other co-inventors assigned all of their rights, title and interest relating to a patent application concerning the assay method in return for revenue sharing upon commercialization of the assay method. We also agreed to pay certain legal fees on behalf of the assignors, which we are entitled to recoup out of any future royalties payable under the revenue sharing provisions. We assigned to the Dr. Small and the co-inventors a non-exclusive, personal, non-sublicensable, non-transferable, royalty free, worldwide, perpetual and irrevocable license to use for their own research and educational purposes the patent application and any patent arising therefrom. Our obligations under the agreement, including our obligations to file and maintain the patent application or patent arising therefrom, and to pay royalties pursuant to the revenue sharing provisions, with respect to any country, extends from the date of first commercial sale of a product covered by any patent arising from the assigned patent application in such country to the date of expiration or invalidation of all of the valid claims of the patent under which the product is covered.

We have the right to pursue any actions against third parties for infringement of the patent rights pursuant to the patent application at our own expense. Any recovery of damages in such an infringement suit shall be first applied to any of our unreimbursed expenses and legal fees relating to the suit with the balance remaining to be treated as net sales received by us, subject to revenue sharing. The litigation costs incurred and any amounts paid in judgment or settlement by us in an infringement action may be credited against a percentage of the revenue share payable to the assignors for any country in which such costs were incurred.

Under the Consulting Agreement with Dr. Small, we engaged Dr. Small for a three year period, commencing September 1, 2002 and expiring on September 1, 2005, for Australian \$20,000 per year and a grant of stock options for consulting services related to the development of the assay method. The 7,500 stock options granted to Dr. Small are exercisable at \$1.35 per share. Dr. Small assigned to us all right, title and interest in all intellectual property and work product created or developed as a result of Dr. Small's engagement by Axonyx. The Consulting Agreement may be terminated by either party for cause upon 30 days notice if the other party does not timely cure its breach of the agreement.

Terminated Research and Option Agreements

On April 30, 2002, a research project funded by us pursuant to the Sponsored Research Agreement and Option between Axonyx, the Mayo Clinic Jacksonville ("Mayo") and Mayo Foundation for Medical Education and Research ("MFMER") terminated. Studies undertaken during the research project helped to confirm the effects of Phenserine and some of our other compounds on the metabolism of beta-APP. We did not receive notification from Mayo or MFMER that intellectual property arose out of the research project that could have been acquired under the exclusive option granted to us pursuant to the agreement. The parties remain subject to certain provisions of the Sponsored Research Agreement under which Mayo and the principal investigator involved in the research must copy us on any presentations at scientific meetings or publications relating to the research undertaken under the agreement and each party will not use the name of the other party without prior consent of the other party, with some exceptions.

On August 15, 2002, the research project being funded by us under the terms of a Research Agreement with Indiana University signed in August 2001 terminated. The funded studies concerned the effects of Phenserine and

Tolserine on the beta-APP processing of beta-amyloid using *in vitro* studies and *in vivo* studies with transgenic mice. We funded this research project for a one year period at a cost of \$125,000. We did not receive notification from the University of Indiana that intellectual property arose out of the research project that could have been acquired under the exclusive option granted to us pursuant to the agreement. The parties remain subject to certain provisions of the Research Agreement under which the University of Indiana must copy us on any presentations at scientific meetings or publications relating to the research undertaken under the agreement, each party will not use the name of the other party without prior consent of the other party, with some exceptions, and certain confidentiality and indemnification provisions apply.

On October 1, 2002, a three-year research project funded by us pursuant to a Sponsored Research Agreement with the University of Melbourne (Australia) terminated. Under the agreement, we funded a research project at the University of Melbourne to develop a diagnostic test for Alzheimer's Disease. On October 11, 2002 we notified the University of Melbourne that we did not intend to exercise the option to acquire an exclusive worldwide license to three patent applications resulting from the research project. Consequently, we are no longer paying the expenses and fees associated with the filing and prosecution of these patent applications covering the intellectual property resulting from the research project. We do not claim any intellectual property generated during the research project. The parties remain subject to certain provisions of the Sponsored Research Agreement involving payment of taxes, non-disclosure and handling of confidential information, rights to intellectual property generated during the research project, and limitation of liability and indemnity.

On April 1, 2001, we entered into a Research Agreement with Thomas Jefferson University under which we agreed to fund a Gilatide Research Program for two years. The research program concerned a potential pharmaceutical compound named Gilatide and related analog compounds that are designed to enhance memory and cognition. In addition, Thomas Jefferson University granted us an option to acquire from the University a worldwide exclusive license to a patent application pertaining to the Gilatide technology and to any invention arising out of the research program. Thomas Jefferson University was responsible for paying all expenses relating to filing, prosecution and maintenance of the patent application covered by the Research Agreement. In March 2003, we decided not to exercise our option to acquire the rights to the patent application pertaining to Gilatide and the sponsored research concerning Gilatide was terminated. Given our focus on funding the clinical development of Phenserine, we decided not to exercise our option to acquire the patent rights to Gilatide.

H. Marketing and Sales

We do not intend to directly manufacture or market any products we may develop. We intend to license to, or enter into strategic alliances with, larger pharmaceutical and veterinary companies that are equipped to manufacture and/or market our products, if any, through their well developed distribution networks. We may license some or all of our worldwide patent rights to more than one company to achieve the fullest development, marketing and distribution of our products, if any.

I. Patents, Trademarks, and Copyrights

We are substantially dependent on our ability to obtain and maintain patents and proprietary rights for our drug candidates, particularly those relating to Phenserine, our lead drug candidate, and to avoid infringing the proprietary rights of others. We have interests in eight patents issued by the United States Patent and Trademark Office and to four pending patent applications. We obtained exclusive worldwide licenses to three patents and to three patent applications, all of which subsequently became issued patents. We have sublicensed to Serono's subsidiary ARS our rights to two of the eight patents listed below and to one patent application that we owned. We are a co-owner, with the NIH and two co-inventor scientists, of one patent, and the sole owner of another patent concerning a process for producing Phenserine. We are a co-owner, also with the NIH and co-inventor scientists, of two patent applications, and the owner of a patent application relating to an assay method. Associated foreign patents have been issued in most cases and foreign patent applications have been filed associated with the listed patents and patent applications. We will continue to seek to obtain additional licenses from universities and other research institutions.

On February 27, 1997, we obtained an exclusive worldwide license from the NIH's parent agency, the Public Health Service (PHS), to three patents and one patent application relating to Phenserine, Cymserine

(a butyrylcholinesterase inhibitor), their analogs and related acetylcholinesterase and butyrylcholinesterase inhibitory compounds from the laboratory of Dr. Nigel Greig and his collaborators via a sublicense with CURE, LLC. The licensed patent application was subsequently issued as a patent.

We obtained an exclusive worldwide license from New York University to one U.S. patent and one pending continuation application thereof from the laboratory of Dr. Blas Frangione at the NYU School of Medicine through a research and license agreement entered into with NYU, effective April 1, 1997. The continuation patent application licensed from NYU, relating to peptides that inhibit formation of amyloid or amyloid-like deposits, was a continuation of U.S. Patent 5,948,763 issued September 7, 1999, concerning certain claims not included in that issued patent, was subsequently issued in the U.S. on October 8, 2002. The NYU patent and the subsequently issued continuation patent relate to the AIPs and PIPs. These patent rights have been sublicensed to ARS, a subsidiary of Serono International, S.A.

A patent directed to certain highly selective butyrylcholinesterase inhibitors, including PENC and Bisnorcymserine, resulting from a collaboration between Dr. Hausman of Axonyx and Dr. Greig of the NIH, was issued on June 25, 2002. The patent relates to the pharmaceutical compounds and their use in the early diagnosis and treatment of AD and related conditions. This patent is jointly owned by Axonyx, the NIH, and two scientists involved in the research.

Co-ownership of a patent based on co-inventorship in the United States means that each co-inventor presumptively owns a pro-rata undivided interest in the whole patent, and has the unilateral right to exploit the patent without the consent of and without accounting to the other owners. None of the co-inventors can unilaterally grant exclusive rights to the patent to another party, nor can any co-inventor prosecute an infringement action without joining the other co-inventors. Ownership laws may vary in other countries.

Issued United States Patents

U.S. Patent 5,171,750 issued December 15, 1992 for "Substituted Phenserines as Specific Inhibitors of Acetylcholinesterase". Expires December 15, 2009.

U.S. Patent 5,378,723 issued January 3, 1995 for "Carbamate Analogs of Thiaphysovenine and Method for Inhibiting Cholinesterases". Expires January 3, 2012.

U.S. Patent 5,409,948 issued April 25, 1995 for "Method for Treating Cognitive Disorders with Phenserine". Expires December 15, 2009.

U.S. Patent 5,998,460 issued December 7, 1999 for "Phenylcarbamates of (Eseroline, (N1-Noreseroline and (N1-Benzylnoreseroline: Selective Inhibitors of Acetyl and Butyrylcholinesterase, Pharmaceutical Compositions and Method of Use Thereof." Expires December 7, 2016.

U.S. Patent 5,948,763 issued September 7, 1999 for "Peptides and Pharmaceutical Compositions thereof for Treatment of Disorders or Diseases Associated with Abnormal Protein Folding into Amyloid or Amyloid-like Deposits". Expires June 6, 2015. Sublicensed by Axonyx to ARS, a subsidiary of Serono.

U.S. Patent 6,410,747 issued June 25, 2002 for "Highly Selective Butyrylcholinesterase Inhibitors for the Treatment and Diagnosis of Alzheimer's Disease and Dementia". Expires July 9, 2018.

U.S. Patent 6,462,171 issued October 8, 2002 for "Peptides and Pharmaceutical Compositions thereof for Treatment of Disorders or Diseases Associated with Abnormal Protein Folding into Amyloid or Amyloid-like Deposits". Expires June 6, 2015. Sublicensed to ARS, a subsidiary of Serono.

U.S. Patent 6,495,700 B1 issued December 17, 2002 for "A Process for Producing Phenserine and its Analogs". Expires January 9, 2022.

U.S. Patent 6,683,105 issued January 27, 2004 for "Highly selective butyrylcholinesterase inhibitors for the treatment and diagnosis of Alzheimer's disease and dementias" Expires June 9, 2018. This patent is jointly owned by Axonyx, the NIH, and two scientists involved in the research, on a co-inventorship basis.

U.S. Patent 6,689,753 issued February 10, 2004 for "Beta sheet breaker peptide analogs that inhibit Beta pleated sheet formation in amyloid Beta-peptide." Expires November 4, 2020.

These patents can expire earlier if they are allowed to abandon or are not adequately maintained.

Patents Pending

Note that we cannot assure you that corresponding patents will be issued or that the scope of the coverage claimed in the following patent applications will not be significantly reduced prior to any patent being issued.

On March 22, 2002, we filed a provisional patent application resulting from a collaboration between Gosse Bruinsma, M.D. of Axonyx and Dr. Nigel Greig of the NIH/NIA, on a co-inventorship basis, covering a method for treating patients with Alzheimer's disease and other cognitive disorders with PosiphenTM, a potential pharmaceutical compound that is the positive isomer of Phenserine. Axonyx and the NIH/NIA jointly own this patent application. Corresponding foreign and U.S. patent applications were filed claiming priority to this patent application.

We have ownership rights, pursuant to assignment by the inventors, to a provisional patent application filed July 1, 2002 entitled "Assay Method". This patent application was assigned to us pursuant to an Intellectual Property Agreement signed in September 2002. The assay method involves a process for screening potential drug compounds for Alzheimer's disease that have an effect on beta-amyloid. We are funding research related to this patent application at the laboratory of Dr. David Small at the Monash University in Australia. Corresponding foreign and U.S. patent applications were filed claiming priority to this patent application.

In 2004, Axonyx filed a U.S. provisional patent application covering a method of treating type II diabetes or diabetic complications with phenserine and/or PosiphenTM. A corresponding Patent Cooperation Treaty ("PCT") patent application was timely filed in 2005 claiming priority to this patent application.

In 2004, Axonyx filed a U.S. provisional patent application covering a method for treating cognitive disorders using a combination of phenserine and PosiphenTM. A corresponding PCT patent application was timely filed in 2005 claiming priority to this patent application.

In 2004, Axonyx filed a U.S. provisional and a Canadian patent application claiming a method for increasing the dosage of phenserine to reduce cholinergic overstimulation. A corresponding PCT patent application is being prepared for timely filing in 2005 claiming priority to these patent applications.

In 2004, Axonyx filed a U.S. provisional patent application claiming a method of treating cognitive impairments associated with Down Syndrome with phenserine and/or PosiphenTM. A corresponding PCT patent application is being prepared for timely filing in 2005 claiming priority to this patent application.

In 2004, Axonyx filed a U.S. provisional patent application covering a method for treating cognitive disorders using a combination of phenserine and memantine. A corresponding PCT patent application is being prepared for timely filing in 2005 claiming priority to this patent application.

In 2004, Axonyx filed other U.S. provisional patent applications, none of which have yet been foreign filed or published. At this time, the content of these provisional patent applications is considered to be trade secret information of Axonyx.

In 2004, Axonyx purchased the US and existing non-US patent rights of Message Pharmaceutical to various filed patent applications exemplified by PCT International Publication Number WO 02/048150 A2 for Agents Useful for Reducing Amyloid Precursor Protein and Treating Dementia and Methods of Use Thereof. These patent applications are now jointly owned by Axonyx, the NIH, and two scientists involved in the research, on a co-inventorship basis.

Axonyx filed a U.S. trademark application for "POSIPHEN". Axonyx presently intends to timely file foreign trademark applications.

We have not filed for any copyright protection to date.

J. Employees

We currently have five full time employees, two of whom are in administration, two of whom are involved in both management and research and development and one of whom is involved in management. See Item 10, Executive Compensation, for information on Axonyx's employment arrangements with certain of its officers and directors.

OXIS had eleven full time employees in the United States at December 31, 2004.

Item 2. Properties.

During 2004, our operations were conducted from our offices in New York, New York and Stevenson, Washington. On January 2, 2004, following the resignation of Mr. Michael Espey, the offices in Seattle were closed. We lease approximately 800 square feet of office space in New York on a three month renewable basis at a rental rate of \$9,800 per month. We leased 144 square feet of office space in Seattle on a three month renewable basis at a rental rate of \$900 per month. This lease terminated in February 2004 and was not renewed. Up until October 2002, we rented 1,000 square feet of office space in Stevenson, Washington on a month to month basis at a rental rate of \$2,500 per month. Up until December 2002, we rented 900 square feet of office space in Wilton, Connecticut on a month to month basis at a rental rate of \$1,250 per month.

OXIS occupies pursuant to leases expiring in November 2005, office, laboratory and manufacturing space in 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.

Axonix Europe BV, a wholly owned subsidiary of Axonix Inc., rents 650 square feet of office space in Leiden, The Netherlands, on a month to month basis at a rental rate of Euro 550 per month.

Item 3. Legal Proceedings.

Please see the description of the purported shareholder class action lawsuits filed in February 2005 described under "Item 1 — Business — Recent Events."

Item 4. Submission of Matters to a Vote of Security Holders

Axonix did not submit any matters to a vote of its stockholders in the fourth quarter of 2004.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is traded on the Nasdaq SmallCap Market under the symbol "AXYX". The following table sets forth the high and low bid quotations for our common stock for the period between January 1, 2003 and February 28, 2005. These quotations reflect prices between dealers, do not include retail mark-ups, mark-downs, and commissions and may not necessarily represent actual transactions.

<u>Period</u>	<u>High</u>	<u>Low</u>
2003		
Quarter ended 3/31/03	\$1.28	\$0.55
Quarter ended 6/30/03	\$4.18	\$0.90
Quarter ended 9/30/03	\$5.40	\$1.96
Quarter ended 12/31/03	\$5.37	\$3.44
2004		
Quarter ended 3/31/04	\$7.85	\$4.60
Quarter ended 6/30/04	\$8.75	\$4.58
Quarter ended 9/30/04	\$5.85	\$3.24
Quarter ended 12/31/04	\$7.49	\$4.05
2005		
Period beginning 1/1/05 and ending 2/28/05	\$6.28	\$1.41

The transfer agent of Axonix is Nevada Agency and Trust Company, 50 West Liberty Street, Suite 880, Reno, Nevada 89501.

As of February 28, 2005 there were approximately 392 holders of record of Axonix's common stock, of which 53,665,518 shares were issued and outstanding.

We have never paid cash dividends on its common stock. We presently intend to retain future earnings, if any, to finance the expansion of our business and we do not anticipate that any cash dividends will be paid in the foreseeable future. Our future dividend policy will depend on our earnings, capital requirements, expansion plans, financial condition and other relevant factors.

Recent Sales of Unregistered Securities; Use of Proceeds From Registered Securities

In May 2004, the Company completed a private placement for \$20 million of securities through the sale of 3,076,923 shares of common stock at \$6.50 per share with new institutional investors. This placement also involved the acquisition by the investor group of five-year warrants to purchase an additional 923,077 shares of the Company's stock at an exercise price of \$8.50 per share. These shares and warrants were subsequently registered.

On January 8, 2004, the Company entered into definitive agreements with new and existing institutional investors relating to a private placement of \$50 million of securities through the sale of 9,650,183 shares of common stock at \$5.15 per share. These agreements also involve the acquisition by the investor group of five-year warrants to purchase an additional 2,412,546 shares of the Company's stock at an exercise price of \$7.25 per share. These shares and warrants were subsequently registered.

Also in January 2004, the Company issued 1,618,061 shares of common stock valued at \$8,194,000 in conjunction with the Company's acquisition of 52% of the outstanding voting stock of Oxis International, Inc. These shares were subsequently registered.

Item 6. Selected Financial Data.

	Years Ended December 31,				
	2004	2003	2002	2001	2000
	(Dollars in thousands, except per share data)				
Statement of Operations Data:					
Total Revenues	\$ 2,275	\$ 1,000	\$ 0	\$ 0	\$ 1,605
Research and development expenses	23,741	5,821	3,852	5,153	3,516
General and administrative expenses	8,250	3,459	2,505	3,277	3,482
Loss from operations	(30,883)	(8,280)	(6,357)	(8,430)	(5,393)
Net Loss	(28,780)	(8,106)	(6,256)	(8,144)	(4,870)
Net Loss per share	(.58)	(.30)	(.36)	(.53)	(.33)
Weighted average shares outstanding (in thousands)	49,977	27,207	17,265	15,423	14,716
	December 31,				
	2004	2003	2002	2001	2000
	(Dollars in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and securities ...	\$ 90,591	\$ 28,780	\$ 4,474	\$ 9,115	\$ 10,363
Total assets	101,394	28,815	7,984	9,211	10,457
Accumulated deficit	(62,508)	(33,728)	(25,622)	(19,366)	(11,222)
Total stockholders equity	86,538	26,651	6,679	8,191	9,683

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

THE FOLLOWING DISCUSSION AND ANALYSIS SHOULD BE READ IN CONJUNCTION WITH OUR FINANCIAL STATEMENTS AND THE NOTES THERETO INCLUDED ON PAGES F-1 THROUGH F-23 FOLLOWING THE SIGNATURE PAGES OF THIS ANNUAL REPORT. ALL STATEMENTS IN THIS ANNUAL REPORT RELATED TO AXONYX'S CHANGING FINANCIAL OPERATIONS AND EXPECTED FUTURE GROWTH CONSTITUTE FORWARD-LOOKING STATEMENTS. THE ACTUAL RESULTS MAY DIFFER MATERIALLY FROM THOSE ANTICIPATED OR EXPRESSED IN SUCH STATEMENTS.

A. General.

Since commencement of operations in 1997, our efforts have been principally devoted to research and development activities, including the development of pharmaceutical compounds and product candidates for the diagnosis and treatment of Alzheimer's disease and other neurological disorders, prion-related diseases such as Bovine Spongiform Encephalopathy and Creutzfeldt Jakob Disease, new variant, and recruiting additional scientific and management personnel and advisors, and raising capital.

The Company's lead drug, Phenserine, is a third generation acetylcholinesterase inhibitor, which has progressed to late stage clinical trials. The results of the 1st Phase III trial were announced on February 7, 2005 and the interim results from the Phase IIb trial were announced on March 11, 2005 and are described under "Recent Events — Item 1 Section A." Overall the results from each trial did not show statistically significant improvements over placebo for the protocol's primary endpoints following 26 weeks of treatment. We have halted additional patient recruitment for the ongoing phase III clinical trials in order to evaluate the planned Phenserine clinical development program following recommendations from our Scientific Advisory Board and Safety Steering Committee, as well as our desire to examine opportunities that could optimize further Phenserine development.

In addition to the Phenserine clinical program, we are sponsoring pre-clinical research relating to an assay method for screening drug candidates for Alzheimer's disease. Pursuant to a sublicense agreement with ARS, a subsidiary of Serono International, S.A., ARS is undertaking research and development concerning the development of (1) compounds called Amyloid Inhibitory Peptides which may prevent and reverse the formation of amyloid plaques in AD, and (2) a pharmaceutical compound for prion-related diseases. Given sufficient financial resources, we may, in the future, sponsor further pre-clinical development of Tolserine, another acetylcholinesterase inhibitor, some of our butyrylcholinesterase inhibitors, and initiate pre-clinical development of Posiphen, a compound that appears to decrease the formation of the beta-amyloid precursor protein with potential applications in the treatment of AD.

We generated revenue in the form of an up-front license fee upon the signing of the License Agreement with ARS, a subsidiary of Serono, in 2000. We cannot assure you that licensed compounds or products will reach any particular stage of development requiring a milestone payment, that licensed compounds or products will ever reach the market giving rise to royalty payments or that additional revenues from patent licensing will be generated.

Our current plan of operation for the next 12 months primarily involves research and development activities, including clinical trials, concerning Phenserine, Posiphen and one of our butyrylcholinesterase inhibitors.

Effective September 1, 2002, we entered into a Research Agreement and a Consulting Agreement with David Henry Small, Ph.D., and an Intellectual Property Assignment Agreement with David Henry Small, Ph.D., Marie-Isabel Aquilar, Ph.D., Supundi Subasinghe ("Assignment Agreement"). Each of these agreements relate to the development of an assay method for the rapid screening of potential drug candidates for the treatment of Alzheimer's Disease. The Research Agreement funds a research project concerning further development of the assay method under the guidance of Dr. Small for a three year period commencing October 1, 2002, for Australian \$90,000 (approximately US \$71,370) per year. The research project pursuant to the Research Agreement is being undertaken by Dr. Small at Monash University in Clayton, Australia.

Our actual research and development and related activities may vary significantly from current plans depending on numerous factors, including changes in the costs of such activities from current estimates, currency fluctuations, the results of our research and development programs, the results of clinical studies, the timing of regulatory submissions, technological advances, determinations as to commercial viability and the status of competitive products. The focus and direction of our operations will also be dependent on the establishment of our collaborative

arrangements with other companies, the availability of financing and other factors. If we in-license or out-license rights to some of our drug candidates our development expenses may fluctuate significantly from prior periods.

B. Results of Operations.

Year ended December 31, 2004 Compared with the Year ended December 31, 2003

For the year ended December 31, 2004 we had revenue of \$2,275,000 compared to \$1,000,000 for the year ended December 31, 2003. Revenue in 2004 was derived from the sale of research assays and fine chemicals at OXIS and a licensing agreement at OXIS for \$450,000. In April 2003, Axonyx received a milestone payment of \$1,000,000 from Serono International S.A. (Serono) under the terms of a license agreement for beta-sheet breaker technology that was signed in September 2000. The milestone payment was triggered when Serono initiated a Phase I clinical trial with a beta-sheet breaker peptide for the potential treatment of Alzheimer's disease.

The Company's costs of sales were entirely related to OXIS. The percentage of cost of sales for the year ended December 31, 2004 was 64%.

For the year ended December 31, 2004 we incurred a net loss of \$28,780,000 compared to net loss of \$8,106,000 for the year December 31, 2003.

For the year ended December 31, 2004 we incurred research and development costs of \$23,741,000 compared to \$5,821,000 for the year ended December 31, 2003. The increase in 2004 research and development expenses compared with 2003 is primarily attributable to the start of additional Phenserine clinical trials. In June 2003 we initiated a Phase IIB and first Phase III pivotal trial in Europe. The Phase IIB trial was originally targeted to recruit 75 patients and has subsequently been expanded to recruit 150 patients. The first Phase III trial targeted 375 patients. In June 2004 we initiated a second Phase III trial and incurred start up costs including the initial investigators meeting. In September 2004 we initiated a third Phase III pivotal trial with similar start up costs. Both the second and third Phase III trials have targeted enrollments of 450 patients each. The 2004 research and development expenses reflect the costs of these four trials, compared to only two in 2003. In 2004 our costs for Phenserine clinical trials were \$11,936,000 compared to \$2,775,000 in 2003. Additionally, studies in carcinogenicity and Absorption, Distribution, Metabolism and Excretion (ADME) increase by \$2,900,000 from the same period in 2003.

Chemical, manufacturing and control costs for 2004 were \$2,702,000 compared to \$450,000 in 2003. The increase reflects manufacturing costs of the drug supply needed for existing and expanded trials. Development costs for Posiphen were \$507,000 in 2004 compared to \$67,000 in 2003. Posiphen is the positive isomer of Phenserine and may exhibit the same mechanism of action as Phenserine without the related side effects. Studies on Posiphen commenced in late 2003 and were expanded in 2004.

Total General & Administrative expenses allocated to Research & Development in 2004 amounted to \$988,000 compared to \$743,000 in 2003. The increase is due to executive bonuses awarded in 2004 and increased administration necessitated by the four clinical trials programs ongoing in Europe, two of which were initiated in 2004.

OXIS accounted for \$218,000 of research and development expenses in 2004.

For the year ended December 31, 2004 we incurred General & Administrative costs of \$8,250,000 compared to \$3,459,000 for the year ended December 31, 2003. The increase for year 2004 of \$4,791,000 was due to non-cash stock option charges for consultants of \$1,848,000 compared \$806,000 in 2003, an increase in professional fees of \$909,000 to \$1,742,000 in 2004 from \$833,000 in 2003. The increase in professional fees results from review and analysis of potential merger and acquisition opportunities, increased use of outside counsel, patent activity, Sarbanes Oxley compliance costs and board member fees. Sales, general and administrative expenses relating to OXIS were \$2,525,000.

General and Administrative salaries increased \$319,000 in 2004 over 2003 primarily due to executive and staff bonuses and the addition of a Chief Financial Officer hired in the third quarter of 2003.

Interest income for the year ended December 31, 2004 was \$1,235,000 compared to \$137,000 for the year ended December 31, 2003. The increase in interest income is attributable to an increase in short-term investment balances during the year.

For the year ended December 31, 2004 the loss on foreign exchange was \$83,000 compared to a gain of \$37,000 on foreign exchange for the year ended December 31, 2003. The loss resulted from Euro purchased and utilized to meet vendor payments denominated in Euro and reflects the strength of the Euro currency against the U.S. dollar in 2004.

In 2004 the Company recognized a gain of \$1,154,000 on the issuance of common stock by OXIS International, Inc in accordance with the accounting prescribed by SEC Staff Accounting Bulletin No. 51.

For the year ended December 31, 2004 financing fees were \$856,000 at OXIS resulting principally from the issuance of warrants in connection with short-term debt and the related conversion.

The Company incurs expenses in Euro currency, as currently the Phenserine clinical trials are being conducted in Europe. Additionally, the Company's European office in the Netherlands is funded from the U.S.

Year ended December 31, 2003 Compared with the Year ended December 31, 2002

For the year ended December 31, 2003 we had revenue of \$1,000,000 compared to no revenue for the year ended December 31, 2002. In April 2003 Axonyx received a milestone payment of \$1,000,000 from ARS, a subsidiary of Serono International SA under the terms of a license agreement for beta sheet breaker technology that was signed in September 2000. The milestone payment was triggered when Serono initiated a Phase I clinical trial with a beta sheet breaker peptide for the potential treatment of Alzheimer's disease.

For the year ended December 31, 2003 we incurred a net loss of \$8,106,000 compared to net loss of \$6,256,000 for the year December 31, 2002.

For the year ended December 31, 2003 we incurred research and development costs of \$5,821,000 compared to \$3,852,000 for the year ended December 31, 2002. The increase in 2003 research and development expenses compared with 2002 is primarily due to the initiation of our Phase II beta amyloid trial and our Phase III pivotal cognition trial, both of which commenced in mid-2003.

Our research and development costs incurred in the 12 months ended December 31, 2003 and 2002 consist primarily of development costs for Phenserine, our lead compound for the treatment of Alzheimer's disease.

In 2003 we had costs of \$2,554,000 for Phenserine clinical trials compared with \$117,000 in 2002. The increased amounts for 2003 were due to the initiation, in June 2003, of a Phase IIB beta-amyloid trial involving 75 patients and a pivotal Phase III cognition trial of involving 375 patients. Both of these trials are being conducted in Europe. Chemical manufacturing and control costs for 2003 were \$244,000 compared to \$1,005,000 in 2002. The decrease is because much of the drug supply needed for the trials had been manufactured in 2002. The costs of various studies involving toxicology, carcinogenicity, absorption, distribution, metabolism and excretion (ADME) aggregate \$967,000 compared to \$1,260,000 in 2002. Development costs for Posiphen were \$67,000 in 2003 compared to \$0 in 2002. Studies on Posiphen commenced in late 2003 and will be expanded in 2004.

Costs of various scientific consultants hired to oversee and monitor the Phenserine clinical development process amounted to \$225,000 in 2003. These consultants were new in 2003. In 2002, the Company used its own scientific personnel whose salary costs for 2002 amounted to \$532,000. Our insurance costs for clinical trials in 2003 increased to \$172,000 from \$56,000 in 2002, due to the fact that extensive human trials are being conducted.

Total General & Administrative expenses allocated to Research & Development in 2003 amounted to \$743,000 compared to \$340,000 in 2002. The increase is due to executive bonuses awarded in 2003 and increased travel in necessitated by the two clinical trials programs ongoing in Europe.

For the year ended December 31, 2003 we incurred General & Administrative costs of \$3,459,000 compared to \$2,505,000 for the year ended December 31, 2002. The increase for year 2003 of \$954,000 was due primarily to non-cash stock option charges for consultants of \$806,000 compared \$100,000 in 2002 and total investor relations costs were \$470,000 compared to \$204,000 in 2002. These increases were offset by total professional fees of \$833,000 for 2003 compared to \$1,112,000 in 2002 and total rent costs for the Company of \$83,000 in 2003 compared to \$197,000 in 2002. The rent reduction was due to the company relocating its New York headquarters to less expensive space in March 2003.

Filing fees increased to \$127,000 in 2003 from \$26,000 in 2002, due mainly to increased shares issued in connection with several financings.

General and Administrative salaries increased \$317,000 in 2003 over 2002 primarily due to executive and staff bonuses and the addition of a Chief Financial Officer in 2003. No bonuses were paid in 2002.

Interest income for the year ended December 31, 2003 was \$137,000 compared to \$101,000 for the year ended December 31, 2002. The increase in interest income is attributable to an increase in short term investment balances during the year offset by a decline in short term interest rates in the financial markets.

For the ended December 31, 2003 the gain on foreign exchange was \$37,000 compared to no gain or loss on foreign exchange for the year ended December 31, 2002. The gain resulted from Euros purchased and utilized to meet vendor payments denominated in Euros.

The Company incurs expenses in Euro currency, as currently the Phenserine clinical trials are being conducted in Europe. Additionally, the Company's European office in the Netherlands is funded from the U.S.

C. Liquidity and Capital Resources.

As of December 31, 2004, we had \$90,591,000 in cash and cash equivalents, and \$84,546,000 in working capital.

Net cash used in operating activities for the year ended December 31, 2004 was \$20,452,000 resulting from a net loss of \$28,780,000 and a gain on issuance of subsidiary stock of \$1,154,000, offset in part by an increase in accounts payable and accrued expenses of \$5,720,000, depreciation and amortization of \$889,000, the amortization of deferred financing costs of \$772,000, and stock and option based compensation of \$2,551,000.

Net cash provided from investing activities for the year ended December 31, 2004 was \$276,000 and reflects \$714,000 in cash acquired in the OXIS acquisition offset in part by \$297,000 in patent additions, \$89,000 in equipment costs and \$52,000 in costs related to the OXIS acquisition.

Net cash from financing activities for the year ended December 31, 2004 was \$81,987,000. In January we received net proceeds of \$46,380,000 from a private placement of \$50,000,000 of securities through the sale of 9,650,183 shares of common stock and warrants. In May we received net proceeds of \$18,364,000 from the private placement of \$20,000,000 of securities through the sale of 3,076,923 shares of common stock and warrants. In December 2004, OXIS received net proceeds of \$3,870,000 from a private placement of 12,264,158 shares issuable at December 31, 2004. During 2004, we received proceeds of \$13,236,000 from the exercise of warrants and stock options and OXIS received a corresponding \$137,000.

We currently have contracts with JSW Research of Austria and PPD Global Ltd. to undertake the ongoing Phenserine clinical program. We also have contracts with other CROs to provide services relating to our research and development activities including completing pre-clinical tests on the drug formulations, undertaking carcinogenicity and toxicology studies, ADME studies, bio-assays of blood/urine/plasma samples, drug stability studies and clinical trial drug packaging. Under our Research and License Agreement with New York University, we must pay minimum annual royalty payments of \$150,000 per year beginning in 2004 through the expiration or termination of that agreement. Our current real estate leases are all on a short-term basis.

The table below sets out our current contractual obligations. However, the nature of these contracts with various clinical research organizations is such that work may have to be stopped with very short notice and we will then only be obligated to pay costs incurred to date.

<u>Vendor</u>	<u>Total Contract</u>	<u>Total Paid through December 31, 2004</u>	<u>Total Remaining Contract Liability</u>	<u>2005</u>	<u>2006</u>
Ace Pharmaceuticals	\$ 1,175,411	\$ 724,898	\$ 450,513	\$ 450,513	
Avtech Labs Inc.	612,287	298,735	313,552	313,552	
BioReliance	811,360	670,850	140,510	140,510	
Covance	449,800	302,900	146,900	146,900	
DataMagik	792,698	229,343	563,355	563,355	
InVitro Technologies	553,470	257,680	295,790	295,790	
JSW Research	8,351,705	3,309,715	5,041,990	5,041,990	
Kendle	473,399	355,049	118,350	118,350	
Karolinska Institute (KUS) ..	2,072,148	—	2,072,148	2,072,148	
Lonza	1,413,504	86,400	1,327,104	1,327,104	
MDSPS	30,000	—	30,000	30,000	
Notox	1,439,987	1,164,578	275,409	275,409	
Patheon	719,563	524,656	194,907	180,000	\$ 14,907
PPD	2,883,390	1,668,188	1,215,202	1,215,202	
PSPG, LLC	2,665,920	999,720	1,666,200	1,332,960	\$333,240
Rhodia Inc.	984,500	470,000	514,500	514,500	
Synkem	1,035,315	163,200	872,115	872,115	
Wil Research Labs LLC	1,398,210	836,110	562,100	401,500	\$160,600
Total	<u>\$27,862,667</u>	<u>\$12,062,022</u>	<u>\$15,800,645</u>	<u>\$15,291,898</u>	<u>\$508,747</u>

We plan to finance our needs principally from the following:

- our existing capital resources and interest earned on that capital;
- through future private placement financing or other equity financings.

We believe that we have sufficient capital resources to finance our plan of operation at least through March 31, 2006. However, this is a forward-looking statement, and there may be changes that could consume available resources significantly before such time. Our long term capital requirements and the adequacy of our available funds will depend on many factors, including the eventual contract costs of undertaking the Phenserine Phase III clinical trials, regulatory delays, patent costs for filing, prosecuting, maintaining and defending our patent rights, among others.

We may be periodically seeking potential equity financing, sub-licensing and other collaborative arrangements that may generate additional capital for us in order to support our research and development activities. We cannot assure you that we will generate sufficient additional capital or revenues, if any, to fund our operations beyond the 12 month period ending March 31, 2006, that any future equity financings will be successful, or that other potential financings through bank borrowings, debt or equity offerings, or otherwise, will be available on acceptable terms or at all.

D. Critical Accounting Policies and Estimates.

This discussion and analysis of our financial condition and results of operations are based on our financial statements that have been prepared under accounting principles generally accepted in the United States of America. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could materially differ from those estimates. We have disclosed all significant accounting policies in note B to the financial statements included in this Form 10-K. Our critical accounting policies are:

Principles of consolidation: The consolidated financial statements include the accounts of Axonyx Europe, B.V., a wholly owned subsidiary organized in Holland. The financial statements also include the accounts of OXIS

from the acquisition date of January 15, 2004 when the company acquired approximately 52% of the common voting stock of OXIS. The Company's ownership in OXIS was reduced to 34% on December 31, 2004 as the result of a third party financing by OXIS. Although the Company has less than a majority ownership at December 31, 2004, the accounts of OXIS are consolidated as the Company controls the board of directors through a majority of the OXIS board seats. All intercompany balances and transactions have been eliminated in consolidation.

On February 28, 2005 OXIS announced that Mr. Steven T. Guillen had joined OXIS as President and Chief Executive Officer and as a member of the OXIS Board of Directors. Consequently the Company no longer has a majority of the seats on the OXIS Board, and because the Company's ownership interest now represents 34% of the OXIS shares outstanding, beginning March 1, 2005 OXIS will no longer be consolidated but rather accounted for using the equity method.

Revenue recognition: We defer recognition of revenue from fees received in advance unless they represent the culmination of a separate earnings process. Such deferred fees are recognized as revenue over the term of the arrangement as they are earned, in accordance with the agreement. License fees represent the culmination of a separate earnings process if they are sold separately without obligating us to perform research and development activities or other services. Right to license fees are recognized over the term of the arrangement. Nonrefundable, non-creditable license fees that represent the culmination of a separate earnings process are recognized upon execution of the license agreement. Revenue from the achievement of milestone events stipulated in the agreements will be recognized when the milestone is achieved. Royalties will be recognized as revenue when the amounts earned become fixed and determinable.

Research, development costs: Research and development costs are expensed as incurred.

Stock-based compensation: We account for stock-based employee compensation under the intrinsic value method prescribed by Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees", and related interpretations. We have adopted the disclosure-only provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation" and SFAS No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosure", which was released in December 2002 as an amendment of SFAS No. 123. We follow the fair value based method of accounting for awards to non-employees.

Impairment of Long-Lived Assets: The Company follows statement of Financial Accounting Standard No. 144 "Accounting for the Impairment of Long-Lived Assets". Long-lived asset are reviewed for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. Subsequent impairment assessments could result in future impairment charges. Any impairment charge results in the reduction in the carrying value of long-lived assets and reduces our operating results in the period in which the charge arose.

Accounting for stock sales by subsidiary: The Company accounts for stock sales by a subsidiary (Oxis) in accordance with SEC Staff Accounting Bulletin No. 51. Sales of unissued shares by Oxis result in a change in the carrying value of the subsidiary in the Company's consolidated financials. These gains amounted to \$1,154,000 relating to OXIS in 2004, arising primarily from its December private placement financing, the conversion of bridge loans into common stock and from the exercise of employee stock options throughout the year.

E. 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 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, which is effective July 1, 2005.

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.

In July 2002, the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS No. 146 replaces EITF No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). SFAS No. 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan as was required by EITF No. 94-3. Examples of costs covered by SFAS No. 146 include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing or other exit or disposal activities. SFAS No. 146 was to be applied to exit or disposal activities initiated after December 31, 2002. SFAS No. 146 did not have a material effect on the Company's financial condition and results of operations.

In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities, known as FIN 46. This interpretation of Accounting Research Bulletin No. 51, Consolidated Financial Statements, addresses consolidation by business enterprises of variable interest entities that either (1) do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support, or (2) are owned by equity investors who lack an essential characteristic of controlling financial interest. FIN 46 applies immediately to variable interest entities created after January 31, 2003. With regard to variable interest entities already in existence prior to February 1, 2003, the implementation of FIN 46 has been delayed and currently applies to the first fiscal year or interim period beginning after December 15, 2003. FIN 46 requires disclosure of variable interest entities in financial statements issued after January 31, 2003, if it is reasonable possible that as of the transition date (1) an entity will be the primary beneficiary of an existing variable interest entity that will require consolidation, or (2) an entity will hold a significant variable interest in, or have a significant involvement with, an existing variable interest entity. The Company does not have any entities as of December 31, 2004 that will require disclosure or new consolidation as a result of adopting the provisions of FIN 46. In December 2003, the FASB issued Interpretation No. 46R, Consolidation of Variable Interest Entities (FIN 46R). FIN 46R replaces the same titled FIN 46 that was issued in January 2003. FIN 46R requires the consolidation of a variable interest entity by a company that bears the majority of the risk of loss from the variable entity's activities, is entitled to receive a majority of the variable interest entity's residual returns or both. The provisions of this interpretation are effective for the Company beginning the first quarter of fiscal 2004. The adoption of this interpretation is not expected to have a material effect on the Company's consolidated financial statements or disclosures.

F. Risks and Uncertainties

RISKS AND UNCERTAINTIES

Risks Related to Our Business

You should carefully consider the risks described below in evaluating Axonyx and our business. If any of the following risks actually occur, our business could be harmed. This could cause the price of our stock to decline. This prospectus contains, in addition to historical information, forward-looking statements, including statements about future plans, objectives, and intentions that involve risks and uncertainties. Our actual results may differ materially from the results discussed in the forward-looking statements. Factors that might cause or contribute to these differences include those discussed below and elsewhere in this prospectus.

We have a limited operating history. We have a large accumulated deficit and may never become profitable.

We have a limited operating history upon which investors may base an evaluation of our likely future performance. Since we began operations in 1997 we have been engaged in developing our research programs, recruiting outside directors, employees and key consultants, and consummating patent licensing agreements. To date, we have not had any in-house laboratory facilities in which to conduct any research and will not have any operational laboratories of our own in the near future. We have had only limited revenue from license fees in the amount of \$2.75 million to date. As of December 31, 2004, we had an accumulated deficit of \$62,508,000 and our operating losses are continuing.

We have no products available for sale and we may never be successful in developing products suitable for commercialization.

With the exception of Phenserine and any products developed by OXIS, all of our drug candidates are at an early stage of development and all of our drug candidates will require expensive and lengthy testing and regulatory clearances. None of our drug candidates have been approved by regulatory authorities. We have no products available for sale and we do not expect to 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 drug candidates, including that:

- Our drug candidates will be ineffective, toxic or will not receive regulatory clearances,
- Our drug candidates will be too expensive to manufacture or market or will not achieve broad market acceptance,
- Our candidates may face generic competition by the time they reach the market place and therefore preclude a return on our investment
- Third parties will hold proprietary rights that may preclude us from developing or marketing our drug candidates, or
- Third parties will market equivalent or superior products.

The success of our business depends upon our ability to successfully develop potential drug products from our sponsored research programs.

We cannot assure you that our sponsored research will lead to the successful development of any therapeutic agents. If any potential products are identified, they will require significant additional research, development, and clinical testing, regulatory approval and substantial additional investment prior to commercialization. Any potential products we identify may not be successfully developed, prove to be safe and efficacious in clinical trials, meet applicable regulatory standards, or be capable of being produced in commercial quantities at acceptable costs or be successfully marketed.

Our product candidates may not successfully complete clinical trials required for commercialization, and as a result our business may never achieve profitability.

To obtain regulatory approvals needed for the sale of our drug candidates, we must demonstrate through testing and clinical trials that each drug candidate is both safe and effective for the human population that it was intended to treat. In general, two successful Phase III clinical trials are required. The clinical trial process is complex and the regulatory environment varies widely from country to country. Positive results from testing and early clinical trials do not ensure positive results in the phase III human clinical trials. Many companies in our industry have suffered significant setbacks in Phase III, potentially pivotal clinical trials, even after promising results in earlier trials. The results from our trials, including our current Phase IIB or Phase III Phenserine trials, if any, may show that our drug candidates produce undesirable side effects in humans or that our drug candidates are not safe or effective or not safe or effective enough to compete in the marketplace. Such results could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a drug candidate. Moreover, we, the FDA, or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks or that our drug candidates are not safe or effective enough. Clinical trials are lengthy and expensive. They require adequate supplies of drug substance and sufficient patient enrollment. Patient enrollment is a function of many factors, including:

- the size of the patient population,
- the nature of the protocol (i.e., how the drug is given, and the size and frequency of the dose and use of placebo control),
- the proximity of patients to clinical sites, and
- the eligibility criteria for the clinical trial (i.e., age group, level of symptoms, concomitant diseases or medications etc.).

Delays in patient enrollment or negative trial outcomes can result in increased costs and longer development times. Even if we successfully complete clinical trials, we may not be able to file any required regulatory submissions in a timely manner and we may not receive regulatory approval for the particular drug candidate that was tested.

In addition, if the FDA or foreign regulatory authorities require additional clinical trials, we could face increased costs and significant development delays. Changes in regulatory policy or additional regulations adopted during product development and regulatory review of information we submit could also result in delays or rejections.

We cannot assure you that we will have future revenue or operating profits and you could lose your entire investment.

We expect to incur substantial operating losses for at least the next several years. We currently have limited sources of revenue other than interest income (other than revenues through OXIS where we are the largest shareholder), and we cannot assure you that we will be able to develop other revenue sources or that our operations will become profitable, even if we are able to commercialize any products. Other than interest or similar income, the only revenue that we have realized to date has been fees totaling \$2.75 million paid by Applied Research Systems ARS Holding N.V., a subsidiary of Serono International, S.A., under the terms of the Development Agreement and Right to License and the subsequent License Agreement. If we do not generate significant increases in revenue, at some point in the future we may not be in a position to continue operations and investors could lose their entire investment.

If we fail to comply with the terms of our licensing agreements our licensors may terminate certain licenses to patent rights, causing us to lose valuable intellectual property assets.

Under the terms of our licensing agreements with each of our patent licensors, New York University and CURE, LLC, (our rights to certain patents under the CURE license are via a sublicense to CURE from the United States Public Health Service on behalf of the National Institute of Aging), our exclusive license to the patent rights covering all of our drug candidates may be terminated if we fail to meet our obligations to the licensors.

Under our Research and License Agreement with New York University, as amended, we are obligated to meet certain deadlines for the pre-clinical and clinical development of the licensed AIP and PIP technology, payment of royalties, and filing, maintenance and prosecution of the covered patent rights. Rights to conduct the ongoing drug development of the AIP and PIP technology covered by the NYU agreement are held by Applied Research Systems ARS Holding N.V., a subsidiary of Serono International, S.A., under the terms of our License Agreement with them. NYU can terminate the Research and License Agreement for cause: (a) if we do not cure within 60 days of notice of a material breach or default in the performance or observance of any of the provisions of the agreement or (b) if we fail to pay any amounts due under the agreement, within 30 days after receiving notice from NYU specifying such breach or default, or automatically and (c) immediately without further action, if we discontinue our business or become insolvent or bankrupt.

We are obligated, under the provisions of the License Agreement with CURE, LLC to pay certain royalty payments, pay for the filing, prosecution and maintenance of the patent rights covered by the agreement, meet certain development timelines and comply with certain pass through provisions from the License Agreement between CURE, LLC and the PHS. The reversionary rights provision of the License Agreement sets certain deadlines by which we are to achieve certain development milestones, including commencing clinical trials, for Phenserine. If we fail to comply with the development benchmarks or the commercial development plan, or pay the required penalty fees, then all rights to the patents may, at CURE's election, revert to CURE, and the agreement will terminate.

Certain pass through provisions from the License Agreement between CURE, LLC and the PHS are contained in our License Agreement with CURE, LLC. These pass through provisions are binding on us as if we were a party to the License Agreement with the PHS. Those provisions cover certain reserved government rights to the licensed patents, obligations to meet certain benchmarks and perform a commercial development plan, manufacturing restrictions, as well as indemnification, termination and modification of rights. PHS reserves on behalf of the U.S. government or any foreign government or international organization pursuant to any existing or future treaty or agreement with the U.S. government an irrevocable, nonexclusive, nontransferable, royalty free license for the practice of all inventions licensed pursuant to the License Agreement between CURE and PHS for research or other

purposes. After making the first commercial sale of licensed products until expiration of the agreement, we must use our reasonable best efforts to make the licensed products and processes reasonably accessible to the U.S. public. PHS reserves the right to terminate or modify the License Agreement if it is determined that such action is necessary to meet requirements for public use specified by federal regulations. We are also obligated, under these pass through provisions, to manufacture licensed products substantially in the U.S., unless a written waiver is obtained in advance from the PHS. We undertook to develop and commercialize the licensed products covered by the patents pursuant to a commercial development plan contained in a pass through provision from the CURE-PHS license agreement. If we fail to cure non-compliance with the commercial development plan after notice from CURE within a reasonable period of time, we could be in material breach of the agreement. We have not, as of the date this Reoffer Prospectus, received notice of default of any of our obligations from CURE, LLC, or the PHS.

If we receive written notice of our default or material breach of any of our obligations under the licensing agreements, we must cure the default within ninety days under the license with CURE or sixty days (or concerning payments, 30 days) under the license with New York University, or the relevant licensor may terminate the license. After such termination, we would not be entitled to make any further use whatsoever of the licensed patent rights, or any related licensed know-how. Upon termination of our license agreements, we are required to return the licensed technology to our licensors. Since we sublicensed the technology licensed from New York University to ARS, a subsidiary of Serono, such termination could also cause us to lose some or all of our future revenues under this sublicense agreement or under any other future sublicensing agreements concerning our patent rights to other drug candidates, if any.

The performance of our obligations to the licensors will require increasing expenditures as the development of the licensed drug compounds proceeds. We cannot guarantee that we will be capable of raising the funds necessary to meet our obligations under the license agreements, sublicense part or all of our licensed drug compounds to a third party capable of undertaking the obligations, or fulfill additional licensing obligations.

We do not currently have the capability to undertake manufacturing, marketing, or sales of any potential products and we have limited personnel to oversee out-sourced clinical testing and the regulatory approval process.

We have not invested in manufacturing, marketing or product sales resources. We cannot assure you that we will be able to acquire such resources if and when needed. It is likely that we will also need to hire additional personnel skilled in the clinical testing and regulatory compliance process if we develop additional product candidates with commercial potential. We have no history of manufacturing or marketing. We cannot assure you that we will successfully manufacture or market any product we may develop, either independently or under manufacturing or marketing arrangements, if any, with other companies. We currently do not have any arrangements with other companies, and we cannot assure you that any arrangements with other companies can be successfully negotiated or that such arrangements will be on commercially reasonable terms. To the extent that we arrange with other companies to manufacture or market our products, if any, the success of such products may depend on the efforts of those other companies. We do not currently have the capability to conduct clinical testing in-house and do not currently have plans to develop such a capability. We out-source our clinical testing to contract research organizations. We currently have one employee and certain other outside consultants who oversee the contract research organizations involved in clinical testing of our compounds. We cannot assure you that our limited oversight of the contract research organizations will suffice to avoid significant problems with the protocols and conduct of the clinical trials.

We depend on contract research organizations to do much of our pre-clinical and all of our clinical testing, and we are substantially dependent on an outside manufacturer to develop and manufacture drug product for our lead drug product.

We have engaged and intend to continue to engage third party contract research organizations, or CROs, and other third parties to help us develop our drug candidates. Although we have designed the clinical trials for our drug candidates, the CROs have conducted all of our clinical trials. As a result, many important aspects of our drug development programs have been and will continue to be outside of our direct control. In addition, the CROs may not perform all of their obligations under arrangements with us. If the CROs do not perform clinical trials in a

satisfactory manner or breach their obligations to us, the development and commercialization of any drug candidate may be delayed or precluded. We cannot control the amount and timing of resources these CROs devote to our programs or product candidates. The failure of any of these CROs to comply with any governmental regulations would substantially harm our development and marketing efforts and delay or prevent regulatory approval of our drug candidates. If we are unable to rely on clinical data collected by others, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

We have contracted with or are currently negotiating contracts with several CROs to perform services concerning certain pre-clinical and clinical testing of Phenserine. For example, our subsidiary, Axonyx Europe has contracted with NOTOX Safety and Environmental Research B.V. of Holland to conduct a pre-clinical carcinogenicity study. Other CROs provide or will provide other services, including conducting a Phase I bioavailability clinical trial, a shelf life testing on the final formulation of Phenserine. We have contracted with JSW Research in Austria to undertake the running of our Phase IIb beta-amyloid clinical trial for Phenserine, as well as our recently completed pivotal Phase III clinical trial for Phenserine. We have also contracted with PPD Global Limited to undertake the running of the second and third Phase III clinical trials for Phenserine. Other CROs provide the program management, program quality assurance and quality control service, and data management and analysis for our clinical trials. In the event that any of these CROs fails to perform the services that they have been contracted to perform such failure would likely cause delay in the completion of the relevant drug development program and additional expense incurred in the process of replacing the CRO. Replacement of NOTOX would likely cause a delay in any future NDA submission for Phenserine and it is likely that switching to another vendor would involve paying higher contract costs. Given that we currently have only one person in house and certain outside consultants who will be primarily responsible for overseeing the conduct of the contract research organizations, we cannot assure you that any failure on the part of those CROs will be detected on a timely basis. We have, in the past, engaged Rhodia Chirex, an API or active pharmaceutical ingredient manufacturer, to develop and manufacture Phenserine drug product. While the rights to the proprietary manufacturing processes have been assigned to us and are covered by a patent application, transferring to another manufacturer would create delays in our drug development of Phenserine and would involve higher costs.

If we need additional funds, and if we are unable to raise them, we will have to curtail or cease operations.

Our drug development programs and the potential commercialization of our drug candidates require substantial working capital, including expenses for testing, chemical synthetic scale-up, manufacture of drug substance for clinical trials, toxicology studies, clinical trials of drug candidates, payments to our licensors and potential commercial launch of our drug candidates. Our future working capital needs will depend on many factors, including:

- the progress and magnitude of our drug development programs,
- the scope and results of testing and clinical trials,
- the cost, timing and outcome of regulatory reviews,
- the costs under current and future license and option agreements for our drug candidates, including the costs of obtaining and maintaining patent protection for our drug candidates,
- the costs of acquiring any technologies or additional drug candidates,
- the rate of technological advances,
- the commercial potential of our drug candidates,
- the magnitude of our administrative and legal expenses, including office rent, and
- the costs of establishing third party arrangements for manufacturing.

We have incurred negative cash flow from operations since we incorporated and do not expect to generate positive cash flow from our operations for at least the next several years. Although since January 2004, we have raised approximately \$70 million through financings (less applicable fees) and an additional \$13.2 million through the cash exercise of various warrants and options to purchase our common stock, we expect that additional

financings will be required in the future to fund our operations. We may not be able to obtain adequate financing to fund our operations, and any additional financing we obtain may be on terms that are not favorable to us. In addition, any future financings (which may include the issuance of warrants issued in connection with such financings) could substantially dilute our stockholders. If adequate funds are not available we will be required to delay, reduce or eliminate one or more of our drug development programs, to enter into new collaborative arrangements on terms that are not favorable to us i.e., the collaborative arrangements could result in the transfer to third parties of rights that we consider valuable.

We have been named as a defendant in purported shareholder class action lawsuits.

Several class action lawsuits have been filed against us as described under "Item 1 — Business — Recent Events." We intend to defend against these actions vigorously; however, we do not know what the outcome of these proceedings will be and, if we do not prevail, we may be required to pay substantial damages or settlement amounts. Furthermore, regardless of the outcome, we may incur significant defense costs, and the time and attention of our management may be diverted from normal business operations. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could materially and adversely affect our operations and results. In any event, publicity surrounding the lawsuits and/or any outcome unfavorable to us could adversely affect our reputation and share price.

We are dependent on executive officers and non-employee scientific personnel.

Because of the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific and management personnel. The loss of Gosse B. Bruinsma, M.D., our President and Chief Executive Officer, and/or S. Colin Neill, our Chief Financial Officer and Treasurer, would be detrimental to us. We do not have employment agreements with key scientific personnel who are doing research at the National Institute of Aging related, in some cases, to pharmaceutical compounds licensed via a sublicense to Axonyx, and have no assurance that such personnel will continue to be involved with such research. We do not carry key man insurance on any of our personnel.

There is intense competition for qualified personnel in the areas of our activities, and there can be no assurance that we will be able to continue to attract and retain qualified personnel necessary for the development of our business. Loss of the services of or failure to recruit additional key scientific and technical personnel would be detrimental to our research and development programs and business.

Most of our Scientific Advisors and our other scientific consultants are employed by academic and research institutions, or are self-employed. For this reason, our advisors and consultants will be able to devote only a portion of their time to us depending on their own priorities. In addition, it is possible, in certain circumstances, that inventions or processes discovered by them will not become the property of our company but will be the property of their full-time employers.

Our business could be harmed if we fail to protect our intellectual property.

We have licensed rights to certain patented and patent pending proprietary technology from NYU and CURE, LLC to which we are obligated to pay royalties if we or our sublicensees develop products based upon the licensed technology. Because of the substantial length of time, effort and expense associated with bringing new products through development and regulatory approval to the marketplace, the pharmaceutical industry places considerable importance on patent and trade secret protection for new technologies, products and processes. We have interests in eight patents issued in the United States. We obtained patent rights in six of those patents from our licensors at New York University and CURE, LLC. We sublicensed the rights to two of those six patents to by Applied Research Systems ARS Holding N.V., a subsidiary of Serono International, S.A. We have also filed two patent applications, one in conjunction with the NIH and two co-inventor scientists that have become issued patents in the United States. In addition to the eight issued patents, we have filed four patent applications in the United States. We have co-ownership patent rights to two of these patent applications. We have ownership rights to one of the patent applications pursuant to assignment by the inventors and we have sublicensed the fourth patent application to ARS. We are obligated to pay the filing, prosecution and maintenance expenses with regard to all of these patents and patent applications. We and our licensors have filed patent applications in other countries, and we may seek

additional patents in the future. Our patent position, like that of many pharmaceutical companies, is uncertain and involves complex legal and factual questions for which important legal principles are unresolved. We may not develop or obtain rights to products or processes that are patentable. Even if we do obtain patents, they may not adequately protect the technology we own or have in-licensed. In addition, others may challenge, seek to invalidate, infringe or circumvent any patents we own or in-license, and rights we receive under those patents may not provide competitive advantages to us. Further, the manufacture, use or sale of our products or processes, if any, may infringe the patent rights of others.

We cannot assure you as to the breadth or the degree of protection that any such patents, if issued, will afford us or that any patents based on the patent applications will be issued at all. In addition, we cannot assure you that others will not independently develop substantially equivalent proprietary information or otherwise obtain access to our know-how or that others may not be issued patents that may require licensing and the payment of significant fees or royalties by us for the pursuit of our business.

Several pharmaceutical and biotechnology companies, universities and research institutions may have filed patent applications or received patents that cover technologies similar to ours. Our ability to make, use or sell any of our drug candidates may be blocked by patents that have been or will be issued to third parties that we may not be aware of. The United States patent applications are confidential while pending in the Patent and Trademark Office, and patent applications filed in foreign countries are often first published six months or more after filing. Therefore, until a patent is issued, we have no way of knowing if a third party has a patent that could preclude us from commercializing our drug candidates. Third party patent applications and patents could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If other companies obtain patents with conflicting claims, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. We may not be able to obtain any such license on acceptable terms or at all. Any failure to obtain such licenses could delay or prevent us from pursuing the development or commercialization of our drug candidates, which would adversely affect our business.

Potential litigation concerning patent rights could involve significant expenses and damage our business.

In the United States, the first to invent a technology is entitled to patent protection on that technology. For patent applications filed prior to January 1, 1996, United States patent law provides that a party who invented a technology outside the United States is deemed to have invented the technology on the earlier of the date it introduced the invention in the United States or the date it filed its patent application. In many foreign countries, the first party to file a patent application on a technology, not the first to invent the technology, is entitled to patent protection on that technology. Under the patent laws of most countries, a product can be found to infringe a third party patent if the third party patent expressly covers the product or method of treatment using the product, or if the third party patent covers subject matter that is substantially equivalent in nature to the product or method, even if the patent does not expressly cover the product or method.

While we have not received notification of potential infringement of patents held by third parties, with respect to any of our drug candidates, litigation, patent opposition and adversarial proceedings could result in substantial costs to us. Litigation and/or proceedings could be necessary or may be initiated to enforce any patents we own or in-license, or to determine the scope, validity and enforceability of other parties' proprietary rights and the priority of an invention. The outcome of any of these types of proceedings could significantly affect our drug candidates and technology. United States patents carry a presumption of validity and generally can be invalidated only through clear and convincing evidence.

Under our license agreements with New York University, CURE LLC, ARS, a subsidiary of Serono, and Dr. David Small and co-inventors, we have the right to pursue any actions against third parties for infringement of the patent rights covered by those agreements. Under those arrangements we are obligated to share any recovery over and above that required for reimbursement of our costs and expenses in bringing the infringement action with our licensors, or in the case of ARS, with our licensee, if ARS joins the suit. Under one of those arrangements, our failure to affect the discontinuance of any infringement after a certain period of time can reduce our royalty income. Under our License Agreement with ARS, if, after the expiration of 90 days of notice of any third party infringement by one party to the other, and we have not obtained discontinuance of such infringement or brought

suit against the third party infringer, then the royalty in effect in such country shall be reduced by fifty percent. Such reduced royalty rate shall continue until such infringement ceases.

An adverse outcome of these proceedings could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology, any of which could adversely affect our business. Moreover, the mere uncertainty resulting from the initiation and continuation of any technology related litigation or adversarial proceeding could adversely affect our business pending resolution of the disputed matters.

If we do not exercise our right to prosecute and our licensors institute and prosecute patent proceedings, our rights will depend in part upon the manner in which these licensors conduct the proceedings. In any proceedings they elect to initiate and maintain, these licensors may not vigorously pursue or defend or may decide to settle such proceedings on terms that are unfavorable to us.

Companies and universities that have licensed product candidates to us for clinical development and marketing are sophisticated competitors that could develop similar products to compete with our products.

Licensing product candidates from other companies, universities or individuals does not always prevent them from developing non-identical but competitive products for their own commercial purposes, nor from pursuing patent protection in areas that are competitive with us. The partners who created these technologies are sophisticated scientists and business people who may continue to do research and development and seek patent protection in the same areas that led to the discovery of the product candidates that they licensed to us. The development and commercialization of successful new drugs from our research program is likely to attract additional research by our licensors in addition to other investigators who have experience in developing products for the memory and cognition market. By virtue of the previous research that led to the discovery of the drugs or product candidates that they licensed to us, these companies, universities, or individuals may be able to develop and market competitive products in less time than might be required to develop a product with which they have no prior experience.

Despite the use of confidentiality agreements and/or proprietary rights agreements, which themselves may be of limited effectiveness, it may be difficult for us to protect our trade secrets.

We rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require certain of our academic collaborators, contractors and consultants to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information.

We might face intellectual property claims that may be costly to resolve and could divert management attention.

We may from time to time be subject to claims of infringement of other parties' proprietary rights. We could incur substantial costs in defending ourselves in any suits brought against us claiming infringement of the patent rights of others or in asserting our patent rights in a suit against another company. Adverse determinations in any litigation could subject us to significant liabilities to third parties, require us to seek costly licenses from third parties and prevent us or our sublicensees from manufacturing and selling our potential products.

Third party co-ownership concerning certain of our in-licensed patent rights could affect any future decision to commercialize certain drug candidates.

There are significant risks regarding the patent rights surrounding Bisnorcymserine and Phenethylnorcymserine (PENC), two of our potential butyrylcholinesterase inhibitor drug candidates, and for Posiphen, a potential pharmaceutical compound for the treatment of Alzheimer's Disease that is the positive isomer of Phenserine. Because we do not own the patent rights exclusively, any future decisions to commercialize PENC or Bisnorcymserine, may be adversely impacted due to patent rights held by third parties with whom we do not currently have licensing agreements concerning the patent application covering those drug candidates. In addition, even if our patent rights are not adversely impacted, we may still attempt to obtain licenses from the third party patent holders to reduce or eliminate the risks relating to our development and commercialization efforts. Such

licenses may not be available on acceptable terms or at all and may impair our ability to commercialize PENC, Bisnorcymserine, or Posiphen. A decision not to commercialize these drug candidates could adversely affect our business.

Because we depend on third parties for the acquisition and development of drug candidates, we may not be able to successfully acquire additional drug candidates or commercialize or develop our current drug candidates.

We do not currently nor do we intend to engage in drug discovery for drug candidate acquisition. Our strategy for obtaining additional drug candidates is to utilize the relationships of our management team and scientific consultants to identify drug candidates for in-licensing from companies, universities, research institutions and other organizations. It is possible that we may not succeed in acquiring additional drug candidates on acceptable terms or at all.

If our drug candidates do not achieve market acceptance, our business may never achieve profitability.

Our success will depend on the market acceptance of any products we may develop. The degree of market acceptance will depend upon a number of factors, including the receipt and scope of regulatory approvals, the establishment and demonstration in the medical community of the safety and effectiveness of our products and their potential advantages over existing treatment methods, generic competition and reimbursement policies of government and third party payors. Physicians, patients, payors or the medical community in general may not accept or utilize any product that we may develop.

The carrying value of Technology for Development Products on our balance sheet may face future impairment.

We follow statement of Financial Accounting Standard No 144 "Accounting for the Impairment of Long-Lived Assets". Long-lived asset are reviewed for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. Subsequent impairment assessments could result in future impairment charges. Any impairment charge results in the reduction in the carrying value of long-lived assets and reduces our operating results in the period in which the charge arose. As of December 2004, we determined that no impairment charge was needed to the carrying value of \$6,807,000 on our balance sheet. Impairment charges may be needed in the future.

Risks Related to Our Industry

Potential technological changes in our field of business create considerable uncertainty.

We are engaged in the biopharmaceutical field, which is characterized by extensive research efforts and rapid technological progress. New developments in Alzheimer's disease research are expected to continue at a rapid pace in both industry and academia. We cannot assure you that research and discoveries by others will not render some or all of our programs or product candidates noncompetitive or obsolete.

Our business strategy is based in part upon inhibition of amyloid conformational change and amyloid precursor protein production and processing and the application of these new and unproven technologies to the development of biopharmaceutical products for the treatment of Alzheimer's disease and other neurological disorders. We cannot assure you that unforeseen problems will not develop with these technologies or applications or that commercially feasible products will ultimately be developed by us.

The markets in which we seek to participate are intensely competitive and many of our competitors are better capitalized and have more experience than we do.

There are many companies, both public and private, including well-known pharmaceutical companies, engaged in developing pharmaceutical and biotechnological products for human therapeutic applications in the Alzheimer's disease area. Our major competitors are currently the pharmaceutical companies that are marketing the

acetylcholinesterase inhibitors for the treatment of Alzheimer's disease. The market for such is dominated primarily by Pfizer with its drug Aricept, others are: Warner-Lambert (Cognex), Novartis (Exelon) and, most recently, Johnson and Johnson (Reminyl), have marketed compounds of this type in the United States. Cognex was effectively removed from the market in 1998 due to severe side effects and Aricept currently dominates the market with approximately \$1 billion in U.S. sales in 2003. Several other pharmaceutical companies have acetylcholinesterase inhibitors in human clinical trials. In addition, treatment of moderate to severe AD with Memantine as monotherapy or in combination with donepezil, a commonly prescribed acetylcholinesterase inhibitor. Memantine has a different mechanism of action that is focused on the glutamate pathway. These are large pharmaceutical companies with far ranging capabilities to market their drugs and to develop follow on drug products. Although our lead drug candidate Phenserine is currently in Phase III clinical trials, there can be no guarantees that we will be able to successfully complete these and obtain regulatory approval for Phenserine and such approval, even if obtained, may be years away. In addition we do not have the capability or the resources of marketing a drug and will have to enter into a collaborative relationship with a larger pharmaceutical company in order to market Phenserine. As Phenserine is also an acetylcholinesterase inhibitor, like the currently marketed drugs, unless the data from future Phenserine clinical trials, if any, reflects the general lack of adverse side effects found in previous clinical trials and the unique mechanism of action involving the inhibition of the beta-amyloid precursor protein found in pre-clinical studies, it will be difficult to distinguish Phenserine from the currently market drugs and gain market share.

Certain smaller pharmaceutical companies may also be competitors. Smaller companies may also prove to be competitors through collaborative arrangements with large pharmaceutical and biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations are also becoming increasingly aware of the commercial value of their inventions and are more actively seeking to commercialize the technology they have developed. Many of these companies have substantially greater capital, research and development and human resources and experience than us and represent significant long-term competition for us. In addition, many of these competitors have significantly greater experience than us in undertaking testing and clinical trials of new pharmaceutical products and obtaining FDA and other regulatory approvals. Furthermore, if we or our current or any future licensee is permitted to commence commercial sales of any product, we or our licensee will also be competing with companies that have greater resources and experience in manufacturing, marketing and sales. We have no experience in these areas. These other companies may succeed in developing products that are more effective or less costly than any that may be developed by us or our future licensee and may also prove to be more successful than us or our future licensee in production and marketing. Competition may increase further as a result of the potential advances in the commercial applicability of peptide chemistry and greater availability of capital for investment in these fields. Other companies are engaged in research and product development based on amyloidogenesis and acetylcholinesterase inhibition.

If we successfully develop and obtain approval for our drug candidates, we will face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability of supply, marketing and sales capability, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective or more affordable products, or obtain more effective patent protection, than we do. Accordingly, our competitors may commercialize products more rapidly or effectively than we do, which could hurt our competitive position.

We cannot assure you of FDA approval for our potential products and government regulation may impact our development plans.

The FDA and comparable agencies in foreign countries impose rigorous safety and efficacy requirements on the introduction of therapeutic pharmaceutical products through lengthy and detailed laboratory and clinical testing procedures and other costly and time-consuming procedures. Satisfaction of these requirements typically takes a number of years and varies substantially based upon the type, complexity and novelty of the pharmaceutical compounds. All but two of our drug product candidates are currently in various stages of pre-clinical development and consequently significant regulatory hurdles remain before any application for regulatory approval can be submitted. Only two of our drug product candidates have been tested in human clinical trials. We cannot assure you that the drug candidates currently in development will elicit similar results in human testing to the results in animal testing. We cannot predict with any certainty when we may submit product candidates for FDA or other regulatory approval.

Government regulation also affects the manufacture and marketing of pharmaceutical products. The effect of government regulation may be to delay marketing of our new products, if any, for a considerable period of time, to impose costly procedures upon our activities and to furnish a competitive advantage to larger companies that compete with us. We cannot assure you that FDA or other regulatory approval for any products developed by us will be granted on a timely basis, if at all. Any such delay in obtaining, or failure to obtain, such approvals would adversely affect the marketing of our products and the ability to generate product revenue. Government regulation may increase at any time creating additional hurdles for us. The extent of potentially adverse government regulation which might arise from future legislation or administrative action cannot be predicted.

We are subject to extensive government regulation and may fail to receive regulatory approval that could prevent or delay the commercialization of our products, if any.

Any approval of our drug candidates may be contingent on post-marketing studies or other conditions and the approval of any of our drug candidates may limit the indicated uses of the drug candidate. Further, even if our drug candidates receive regulatory approval, we may still face difficulties in entering into collaborative arrangements for the marketing and manufacturing of those drug candidates. A marketed product, its manufacturer and the manufacturer's facilities are subject to continual review and periodic inspections. The FDA requires that all pre-clinical and clinical testing, as well as manufacturing of drug product, meet certain criteria commonly referred to in our industry as Good Practices guidelines, including Good Manufacturing Processes, Good Laboratory Practices and Good Clinical Practices. In our case, contract research organizations and academic or other sponsored research laboratories that we utilize for our pre-clinical and clinical research, as well as API manufacturing of drug product, must comply with these guidelines. Our contracted manufacturers, sponsored research labs and contract research organizations undertake to adhere to Good Manufacturing Processes, Good Laboratory Practices and Good Clinical Practices. In addition, such guidelines and practices may change, and our compliance such changes may have an adverse effect on our business.

The discovery of non-compliance with regulatory requirements with respect to a product, manufacturer or facility may result in restrictions on the product or manufacturer, including withdrawal of the product from the market. The failure to comply with applicable regulatory requirements can, among other things, result in any or all of the following:

- fines,
- suspended regulatory approvals,
- refusal to approve pending applications,
- refusal to permit exports from the United States,
- product recalls,
- seizure of products,
- injunctions,
- operating restrictions, and
- criminal prosecutions.

Health care reform measures and third party reimbursement practices are uncertain and may adversely impact the commercialization of our products, if any.

The efforts of governments and third party payors to contain or reduce the cost of health care will continue to affect the business and financial condition of drug companies. A number of legislative and regulatory proposals to change the health care system have been proposed in recent years. In addition, an increasing emphasis on managed care in the United States has and will continue to increase pressure on drug pricing. While we cannot predict whether legislative or regulatory proposals will be adopted or what effect those proposals or managed care efforts may have on our business, the announcement and/or adoption of such proposals or efforts could have an adverse effect on our decisions to proceed with the development of our drug candidates and/or adversely effect our potential future

profit margins and financial condition. Sales of prescription drugs depend significantly on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. These third party payors frequently require that drug companies give them predetermined discounts from list prices, and they are increasingly challenging the prices charged for medical products and services. We expect that reimbursement pressures will continue in the future. If we succeed in bringing, through collaborative arrangements, one or more products to the market, these products may not be considered cost effective and reimbursement to the consumer may not be available or sufficient to allow us to sell our products on a competitive basis.

In addition, third-party payors may discontinue or limit reimbursement for, or the use of, the types of drugs being developed by our company. For example, in the United Kingdom, the National Institute for Clinical Excellence recently recommended that National Health Service doctors not prescribe three drugs — Aricept, Exelon and Reminyl — to new patients with mild to moderate dementia on the grounds that they are not worthwhile. These products are competitive with our drug candidate Phenserine. If similar action is taken by regulators in the European Community or the United States, the potential market for Phenserine will be significantly diminished.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

The testing and marketing of drug products entail an inherent risk of product liability. If we cannot successfully defend ourselves against liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. We currently carry clinical trial insurance but do not carry product liability insurance. We currently maintain clinical trial insurance in the amount of \$5,000,000. When we decide that product liability insurance is necessary, we may not be able to obtain product liability insurance at a reasonable cost, if at all. While under various circumstances we are entitled to be indemnified against losses by our corporate collaborators, indemnification may not be available or adequate should any claims arise.

Generic Competition for Alzheimer’s drugs currently on the market could materially impact our future operations.

There are competitive products for phenserine already on the U.S. market. For instance, Aricept™ (donepezil hydrochloride), Reminyl™ (galantamine hydrobromide or “R113675”), and Exelon™ (rivastigmine) are presently being sold in the United States for the treatment of Alzheimer’s Disease. The respective primary patents for these products are set to expire (taking into account patent term extensions under 35 U.S.C. § 156) as follows:

<u>Trademark Name</u>	<u>US Patent</u>	<u>Present Patent Expiration date</u>	<u>Term Extension (granted)</u>	<u>Projected Term Extension</u>
Aricept™	4,895,841	Nov. 25, 2010	Nov. 25, 2010	
Reminyl™	4,663,318	Jan. 15, 2006		Dec. 14, 2008
Exelon™	4,948,807	Aug. 14, 2007		Aug 14, 2012

If we or one of our future prospective competitors who already has a drug on the market cannot successfully defend the patents protecting the products from challenge by a generic drug manufacturer, and a generic manufacturer were thus able to enter the market, our results of operations could be materially adversely affected.

If US Patent 4,663,318 (galantamine hydrobromide) or US Patent 4,948,807 (rivastigmine) expires before the issuance of certificates of patent term extension for the particular patent(s), then a competitor selling generic versions of the drug(s) could attempt to enter the market in 2006 or 2007, respectively. Such an event, could materially adversely affect our results of operations.

Other Risks

We do not pay cash dividends.

We have never paid dividends and do not presently intend to pay any dividends in the foreseeable future.

There is only a limited trading market for our common stock and it is possible that you may not be able to sell your shares easily.

There is currently only a limited trading market for our common stock. Our common stock trades on the Nasdaq SmallCap Market under the symbol "AXYX" with, until recently, very limited trading volume. We cannot assure you that a substantial trading market will be sustained for our common stock.

The market price of our stock may be adversely affected by market volatility.

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors,
- developments with respect to patents or proprietary rights,
- announcements of technological innovations by us or our competitors,
- announcements of new products or new contracts by us or our competitors,
- actual or anticipated variations in our operating results due to the level of drug development expenses and other factors,
- changes in financial estimates by securities analysts and whether our potential earnings or losses meet or exceed such estimates,
- conditions and trends in the pharmaceutical and other industries including the successful market launch of competing products or unfavorable pricing conditions,
- new accounting standards,
- general economic, political and market conditions and other factors, and
- the occurrence of any of the risks described in these "Risk Factors."

In the past two years, the price range of the bid quotations for our common stock has been between a high of \$8.75 and a low of \$0.55. In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation, such as the lawsuits that have recently been filed against us, has often been instituted against those companies. Please see the risk factor above entitled "We have been named as a defendant in purported shareholder class action lawsuits."

Declines in our stock price might harm our ability to issue equity under future potential financing arrangements. The price at which we issue shares in such transactions is generally based on the market price of our common stock and a decline in our stock price would result in our needing to issue a greater number of shares to raise a given amount of funds or acquire a given amount of goods or services. For this reason, a decline in our stock price might also result in increased ownership dilution to our stockholders.

The future issuance of common stock upon exercise of warrants and stock options may depress the price of our common stock.

As of February 28, 2005, we had outstanding options to purchase an aggregate of 4,777,000 shares of our common stock to our employees, officers, directors, and consultants under our existing option plans. We may issue options to purchase an additional 3,392,000 shares of our common stock under the option plans.

In addition, we have granted options to purchase an aggregate of 343,000 shares of common stock outside of our stock option plans to consultants and others. These options were all granted prior to June 30, 2003.

There are currently outstanding warrants to purchase an aggregate of 7,587,000 shares of common stock.

During the respective terms of the warrants and options granted or to be granted under our stock option plans or otherwise, the holders thereof are given an opportunity to benefit from a rise in the market price of the common stock, with a resultant dilution of the interests of existing stockholders. The existence of these warrants and options could make it more difficult for us to obtain additional financing while such securities are outstanding. The holders may be expected to exercise their rights to acquire common stock and sell at a time when we would, in all likelihood, be able to obtain needed capital through a new offering of securities on terms more favorable than those provided by these warrants and options. During the respective terms of the warrants and options granted or to be granted under our stock option plans or otherwise, the holders thereof are given an opportunity to benefit from a rise in the market price of the common stock, with a resultant dilution of the interests of existing stockholders. The existence of these warrants and options could make it more difficult for us to obtain additional financing while such securities are outstanding. The holders may be expected to exercise their rights to acquire common stock and sell at a time when we would, in all likelihood, be able to obtain needed capital through a new offering of securities on terms more favorable than those provided by these warrants and options.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We have foreign currency accounts that are exposed to currency exchange risk. These foreign currency accounts have been utilized to fund the operations of our wholly owned subsidiary, Axonyx Europe, based in the Netherlands. We had a net foreign exchange loss for the fiscal year ended December 31, 2003 of \$83,000. If the foreign currency rates were to fluctuate by 10% from rates at December 31, 2004 and 2003, the effect on our financial statements would not be material. However, there can be no assurance there will not be a material impact in the future. In 2003, we adopted a policy to limit the purchase of foreign currencies to the amounts necessary to cover firm contractual commitments in foreign currencies for the forward six months. However, as long as we continue to fund our foreign operations, we will be exposed to some currency exchange risks. The majority of our ongoing clinical trials are being conducted in Europe.

We consider our investments in money market accounts, short-term commercial paper and time deposits as cash and cash equivalents. The carrying values of these investments approximate fair value because of the short maturities (three months or less) of these instruments and accounts. Therefore, changes in the market's interest rates do not affect the value of the investments as recorded by us.

We do not enter into or trade derivatives or other financial instruments or conduct any hedging activities.

Item 8. Financial Statements and Supplementary Data.

The Audited Financial Statements for this Form 10-K appear on pages F-1 through F-23 following the signature page below.

Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this annual Report on Form 10-K. Based on this evaluation, our principal executive officer and principal financial officer concluded that these disclosure controls and procedures are effective and designed to ensure that the information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the requisite time periods. Our management's conclusion does not take into account, and our management has not made any evaluation of, any disclosure controls and

procedures of OXIS International, Inc., in which we acquired a 52% interest in January 2004 (our interest at December 31, 2004 had been reduced to 34% due an equity issuance by OXIS).

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. 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 or deviations, if any within the company have been detected. While we believe that our disclosure controls and procedures have been effective, in light of the foregoing, we intend to continue to examine and refine our disclosure control and procedures to monitor ongoing developments in this area.

Management's Annual Report on Internal Control Over Financial Reporting

This information has been omitted as permitted by an SEC order under Section 36 of the Securities Exchange Act of 1934, and will be provided in an amendment to this Form 10-K.

Attestation Report of the Registered Public Accounting Firm

This information has been omitted as permitted by an SEC order under Section 36 of the Securities Exchange Act of 1934, and will be provided in an amendment to this Form 10-K.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended) identified in connection with the evaluation of our internal control performed during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors and Executive Officers of the Registrant

A. Directors, Executive Officers, Promoters and Control Persons

The current executive officers, directors and significant employees of Axonyx are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Marvin S. Hausman, M.D.	63	Chairman of the Board, Director
Gosse B. Bruinsma, M.D.	50	President & Chief Executive Officer President of Axonyx Europe BV, Director
S. Colin Neill	58	Chief Financial Officer, Treasurer & Secretary
Louis G. Cornacchia	71	Director
Steven H. Ferris, Ph.D.	61	Director
Gerard J. Vlak, Ph.D.	71	Director
Ralph Snyderman, M.D.	65	Director
Michael A. Griffith	46	Director

Each director is elected to hold office for a one year term or until the next annual meeting of stockholders and until his successor is elected and qualified. The officers of Axonyx serve at the pleasure of Axonyx's Board of Directors.

The following sets forth certain biographical information with respect to the directors and executive officers of Axonyx.

Marvin S. Hausman, M.D. On March 3, 2005 Dr. Hausman resigned as Chief Executive Officer, but remains Chairman of the Board. Marvin Hausman had served as a director and President & CEO of Axonyx since January 1997. At the 2002 Annual Meeting of Stockholders held on June 11, 2002 Dr. Hausman was reelected as a director of Axonyx to serve until the 2003 Annual Meeting of Stockholders. At a Board Meeting on June 11, 2002, Dr. Hausman was reelected as President and Chief Executive Officer of Axonyx to serve until the Board of Directors meeting to be held as soon as possible after the 2003 Annual Meeting of Stockholders. Dr. Hausman was a co-founder of Medco Research Inc., a pharmaceutical biotechnology company specializing in adenosine products. He has thirty years experience in drug development and clinical care. Dr. Hausman received his medical degree from New York University School of Medicine in 1967 and has done residencies in General Surgery at Mt. Sinai Hospital in New York, and in Urological Surgery at U.C.L.A. Medical Center in Los Angeles. He also worked as a Research Associate at the National Institutes of Health, Bethesda, Maryland. He has been a Lecturer, Clinical Instructor and Attending Surgeon at the U.C.L.A. Medical Center Division of Urology and Cedars-Sinai Medical Center, Los Angeles. He has been a Consultant on Clinical/Pharmaceutical Research to various pharmaceutical companies, including Bristol-Meyers International, Mead-Johnson Pharmaceutical Company, Medco Research, Inc., and E.R. Squibb. Since October 1995 Dr. Hausman has been the President of Northwest Medical Research Partners, Inc., a medical technology and transfer company. Dr. Hausman served on the board of directors of Oxis International, Inc. ("Oxis") from March 2002 to November 2003. He was a member of the board of directors of Medco Research, Inc. from inception (1978) through 1992 and from May 1996 to July 1998. Dr. Hausman was a member of the board of directors of Regent Assisted Living, Inc., a company specializing in building assisted living centers including care of senile dementia residents, from March 1996 to April 2001. Dr. Hausman currently serves as Chairman of the Board of Oxis, in which our company holds a 34% interest.

Gosse B. Bruinsma, M.D. Gosse Bruinsma has served as President of Axonyx Europe BV since its formation in October 2000. Dr. Bruinsma has served as the Chief Operating Officer of Axonyx since February 2001 and was Treasurer of Axonyx until September 2003. On March 3, 2005, we announced that Dr. Bruinsma has become the CEO of our company. At the 2002 Annual Meeting of Stockholders held on June 11, 2002 Dr. Bruinsma was elected as a director of Axonyx to serve until the 2003 Annual Meeting of Stockholders. At a Board Meeting on June 11, 2002, Dr. Bruinsma was elected as Chief Operating Officer of Axonyx to serve until the Board of Directors meeting to be held as soon as possible after the 2003 Annual Meeting of Stockholders. In September 2003, Dr. Bruinsma was appointed President of Axonyx Inc. Dr. Bruinsma has over 15 years experience in the medical, pharmaceutical and biotechnology fields. Dr. Bruinsma received his undergraduate degree from McGill University, Montreal and received his medical degree from the University of Leiden, the Netherlands. He joined the pharmaceutical industry to become European Medical Director for Zambon, Milan. He subsequently joined the international contract research organization, ClinTrials Research, to become their Vice President for Medical and Regulatory Affairs. In September 1995 Dr. Bruinsma joined Forest Laboratories in New York as Medical Director, with medical responsibility for their anti-hypertensive product launch, HRT program, Cervidil®, and their urological disease projects. From September 1997 to 1999 Dr. Bruinsma was General Manager and Vice-President Development for Chrysalis Clinical Services Europe based in Switzerland. From November 1999 until he joined Axonyx Europe BV, Dr Bruinsma was the Vice President Development for Crucell BV (formerly IntroGene), a biotechnology company based in the Netherlands.

S. Colin Neill Mr. Neill joined Axonyx Inc. in September 2003 as Chief Financial Officer and Treasurer and was named Secretary in January 2004. From April 2001 to September 2003, Mr. Neill had been an independent consultant assisting small development stage companies raise capital. Previously Mr. Neill served as Senior Vice President, Chief Financial Officer, Secretary and Treasurer of ClinTrials Research Inc., a \$100 million publicly traded global contract research organization in the drug development business, from 1998 to its successful sale for \$125 million in cash in April 2001. Prior to that Mr. Neill served as Vice President and Chief Financial Officer of Continental Health Affiliates Inc. and its majority owned subsidiary Infu-Tech Inc., a \$ 70 million network of health care companies focused on home health, long term care, assisted living and managed care. Mr. Neill's career experience has included that of Acting Vice President Finance and Chief Financial Officer of Pharmos Corporation, a biopharmaceutical company in the business of developing novel drug technologies. Earlier experience was gained as Vice President Finance and Chief Financial Officer of BTR Inc., a \$3.5 billion US subsidiary of BTR plc, a British

diversified manufacturing company, and Vice President Financial Services of The BOC Group Inc. a \$2.5 billion British owned industrial gas company with substantial operations in the health care field. Mr. Neill served for four years with American Express Travel Related Services, firstly as chief internal auditor for worldwide operations and then as head of business planning and financial analysis. Mr. Neill began his career in public accounting with Arthur Andersen LLP in Ireland and later with Price Waterhouse LLP as a senior manager in New York City. He also served with Price Waterhouse for two years in Paris, France. In March 2004, Mr. Neill was designated as a director of Oxis and currently serves on the Oxis Board of Directors.

Mr. Neill graduated from Trinity College, Dublin with a first class honors degree in Business/Economics and he holds a masters degree in Accounting and Finance from the London School of Economics. He is both a Certified Public Accountant (CPA) in New York State and a Chartered Accountant (FCA) in Ireland.

Louis G. Cornacchia Mr. Cornacchia has served as a director of Axonyx since February 21, 2003, when he was elected by the Board to serve until the 2003 Annual Meeting of Stockholders. Louis Cornacchia has extensive experience in managing several engineering consultancy companies. Louis Cornacchia received a bachelors in Electrical Engineering from Manhattan College in 1955. Between 1955 and 1963, Mr. Cornacchia was employed as an RF engineer at Hazeltine Electronics Corp., at the Loral Systems Design Team where he worked on design of countermeasures/reconnaissance systems, and subsequently was employed as Chief Engineer at Victory Electronics developing light imaging scopes for the U.S. Army. In 1963 Mr. Cornacchia joined Norden Systems where he worked as a Test Equipment Manager for the F111D avionics program. In 1969, Mr. Cornacchia formed Collins Consultants International, Ltd., an engineering consultancy providing services to Norden Systems and multiple defense engineering companies. In 1974, Mr. Cornacchia formed Charger Tech Services, another engineering services company. In 1987, Mr. Cornacchia formed Scinetics, an engineering consultancy that provides microwave wireless engineering services. Scinetics provides engineering services for mobile cellular and PCS wireless companies, assisting them in obtaining approvals for seamless wireless networks. Mr. Cornacchia is presently the President of Scinetics. Mr. Cornacchia has also served as Chairman of the Board of Directors of Reliance Bank, White Plains, New York (1992-1995) and as a member of the Advisory Board of Patriot National Bank, Stamford, Connecticut (1995-2000).

Steven H. Ferris, Ph.D. Dr. Ferris has served as a director of Axonyx since January 6, 2003, when he was elected by the Board to serve until the 2003 Annual Meeting of Stockholders. Dr. Ferris is a neuropsychologist, psychopharmacologist, and gerontologist who has been studying brain aging and Alzheimer's disease for over thirty years. Dr. Ferris is the Friedman Professor of the Alzheimer's Disease Center in the Department of Psychiatry at New York University (NYU) School of Medicine, Executive Director of NYU's Silberstein Institute for Aging and Dementia and Principal Investigator of their Alzheimer's Disease Center. Dr. Ferris has been at the NYU School of Medicine since 1973, where he has conducted a major research program focusing on cognitive assessment, early diagnosis and treatment of brain aging and Alzheimer's disease. He has served as the Associate Editor in Chief of *Alzheimer Disease and Associated Disorders*, is a member of the Medical and Scientific Affairs Council of the national *Alzheimer's Association*, has served on several NIH peer review panels, and has been a member of the FDA Advisory Committee which reviews new drugs for Alzheimer's disease. He has conducted more than 50 clinical trials in aging and dementia and has been a consultant to numerous pharmaceutical companies who are developing new treatments for Alzheimer's disease.

Gerard J. Vlak, Ph.D. Gerard Vlak has served as a director of Axonyx since February 21, 2003, when he was elected by the Board to serve until the 2003 Annual Meeting of Stockholders. Gerard Vlak has more than thirty years experience in corporate management and has considerable experience serving on corporate boards. Dr. Vlak received a doctorate in Macro-Economics from the University of Tilburg in The Netherlands in 1967. He has served as a Full Professor of Monetary Economics at Erasmus University in Rotterdam, The Netherlands and as a part-time Professor of Monetary Economics at V.E.H. Economic University in Brussels, Belgium. From 1969 to 1988, Dr. Vlak was a member of the Executive Board of Rabobank Nederland. At Rabobank Nederland, Dr. Vlak managed the corporate and international banking departments and was the Chairman of the Credit Committee. He also set up and managed the U.S. operations of the bank through a new Federal Branch in New York. After retirement from Rabobank in 1988, Dr. Vlak was a Regional Manager for the United States and Canada at the Amsterdam-Rotterdam Bank, N.V., and later, was the Executive Vice President and Chief Financial Officer of ABN-AMRO Bank USA. From 1992 to the present, Dr. Vlak has been a member of the Board of Trustees of Bank Julius Baer Investment Funds and a member of the Board of Directors of Océ'-USA Holding, Inc.

Ralph Snyderman, M.D. Dr. Ralph Snyderman was appointed a Director of the Company effective March 8, 2004. Dr. Snyderman is currently Chancellor Emeritus at Duke University. Previously, he served as Chancellor for Health Affairs, Executive Dean of the School of Medicine, and James B. Duke Professor of Medicine, Duke University Medical Center and President and Chief Executive Officer of the Duke University Health System, one of the few fully integrated health systems in the country. Additionally, Dr. Snyderman serves as a member of the board of directors of Proctor and Gamble Inc., Cardiome Pharma Corporation, and SAIC. Dr. Snyderman received his M.D., magna cum laude, in 1965 from the Downstate Medical Center of the State University of New York and he served his internship and residency in medicine at Duke. Pre-eminent in his field of immunology, Dr. Snyderman is internationally recognized for his research contributions to our understanding of inflammation that have led to numerous important discoveries published in nearly 350 manuscripts over the last 25 years.

Michael A. Griffith, Michael A. Griffith has served on the Axonyx Board of Directors since October 13, 2004. Mr. Griffith is currently Chief Executive Officer of GPD Pharma, a contract pharmaceutical company. Mr. Griffith was formerly Chairman and Chief Executive Officer of ChiRex Inc. (NASDAQ: CHRX), a contract pharmaceutical research and development and contract manufacturer of active pharmaceutical ingredients. Mr. Griffith is currently Chairman of the Board of Directors of Centru Financial Corporation (AMEX: CFF), an Illinois state-chartered bank holding company with over \$600 million in assets that operates 19 branches in 6 counties with 165 employees. Mr. Griffith is currently Chairman of the Board of Trustees of the First Church of Round Hill in Greenwich, Connecticut. A graduate of the J.L. Kellogg Graduate School of Management at Northwestern University, Mr. Griffith was an investment banker for nearly 15 years, including positions as Director of Equity Capital Markets at Credit Suisse First Boston and High Yield Capital Markets at Bankers Trust Company, both in New York.

There are no family relationships between any of the officers and directors.

It is the paramount duty of the Board of Directors to oversee the Chief Executive Officer and other senior management in the competent and ethical operation of the Company on a day-to-day basis and to assure that the long-term interests of the stockholders are being served. To satisfy this duty, the directors set standards to ensure that the Company is committed to business success through maintenance of the highest standards of responsibility and ethics.

Members of the Board bring to the Company a wide range of experience, knowledge and judgment. The governance structure in the Company is designed to be a working structure for principled actions, effective decision-making and appropriate monitoring of both compliance and performance. The key practices and procedures of the Board are outlined in the Corporate Governance Principles. We anticipate that the Corporate Governance Principles will be made available shortly in the "Investor Relations" section of the Company's website at www.axonyx.com.

We have constituted Audit, Nominating and Compensation Committees. The Audit Committee consists of Messrs. Steven Ferris, Lou Cornacchia and Gerard Vlak, who are all outside directors. The Nominating Committee and the Compensation Committee consists of the same three outside directors plus Mr. Michael Griffith.

The Audit Committee oversees our audit activities to protect against improper and unsound practices and to furnish adequate protection to all assets and records. Our Board of Directors has adopted a written Charter for its Audit Committee. Each of the members of this Committee is an "independent director" as defined in Rule 4200 of the Marketplace Rules of the National Association of Securities Dealers, Inc. The Nominating Committee makes proposals to the full Board concerning the hiring or engagement of directors, officers and certain employee positions. The Compensation Committee makes proposals to the full Board for officer compensation programs, including salaries, option grants and other forms of compensation. It is expected that these committees will meet periodically on an informal basis.

At least one member of the Company's Audit Committee qualifies as an "audit committee financial expert" under Item 401(h) of Regulation S-K: Gerard Vlak, Ph.D. is the designated audit committee financial expert, and is considered "independent" as the term is used in Item 7(d)(3)(iv) of Schedule 14A under the Exchange Act.

The Audit Committee, Compensation Committee and Nominating and Governance Committee each operate under written charters adopted by the Board. These charters are filed as exhibits to this annual report on Form 10-K and we anticipate that they will be made available shortly in the "Investor Relations" section of the Company's website at www.axonyx.com.

As part of our system of corporate governance, our Board of Directors in March 2004 adopted a Code of Business Conduct and Ethics that is applicable to all employees and specifically applicable to our chief executive officer, president, chief financial officer and controllers. A copy of the Code of Business Conduct and Ethics is filed as an exhibit to this annual report on Form 10-K and is currently available upon written or telephone request to Axonyx Inc. 500 Seventh Avenue, 10th Floor, New York, NY 10018, (Tel.) 212-645-7704. We anticipate that the Code of Business Conduct and Ethics will be made available shortly in the "Investor Relations" section of the Company's website at www.axonyx.com. We intend to disclose any changes in or waivers from our Code of Business Conduct and Ethics by filing a Form 8-K or by posting such information on our website.

In January 2005, our Board also constituted an Executive Committee, which currently consists of Mr. Michael Griffith, who serves as Chairman, and Drs. Marvin Hausman, Gosse Bruinsma and Ralph Snyderman.

B. Section 16(a) Beneficial Ownership Reporting Compliance.

No person who, during the fiscal year ended December 31, 2004, was a director, officer or beneficial owner of more than ten percent of the Company's Common Stock which is the only class of securities of the Company registered under Section 12 of the Securities Exchange Act of 1934 (the "Act"), a "Reporting Person" failed to file on a timely basis, reports required by Section 16 of the Act during the most recent fiscal year. The foregoing is based solely upon a review by the Company of Forms 3 and 4 during the most recent fiscal year as furnished to the Company under Rule 16a-3(d) under the Act, and Forms 5 and amendments thereto furnished to the Company with respect to its most recent fiscal year, and any representation received by the Company from any reporting person that no Form 5 is required.

Item 11. Executive Compensation.

A. Summary Compensation Table

The table below sets forth the aggregate annual and long-term compensation paid by us during our last three fiscal years ended December 31, 2002, December 31, 2003 and December 31, 2004 to our Chief Executive Officer and each of the highest paid executive officers of Axonyx whose annual salary and bonus for fiscal year 2004 exceeded \$100,000 (collectively, the "Named Executive Officers").

Annual Compensation (5)

<u>Name and Principal Occupation</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)</u>	<u>Other (\$)</u>	<u>Long term Compensation Awards Securities underlying Options (#)</u>
Marvin S. Hausman Dir, Chairman & CEO	2004	\$394,375	\$200,000	\$54,376(5)	200,000
	2003	\$250,000	\$175,000	\$31,719	325,000(4)
	2002	\$246,000	—	\$54,376	75,000
Gosse B. Bruinsma Dir., President & COO (1)	2004	\$372,000	\$150,000	\$31,000	100,000
	2003	\$253,000	\$100,000	\$28,250	300,000(4)
	2002	\$197,000	—	\$23,750	140,000
S. Colin Neill CFO, Sec. & Treas. (2)	2004	\$212,000	\$100,000	\$10,000	50,000
	2003	\$ 52,000	\$ 10,000	\$ 2,915	210,000(4)

- (1) Gosse B. Bruinsma, M.D. became an employee of Axonyx in October 2000. Dr. Bruinsma resides and operates from the Axonyx Europe BV offices in Leiden, The Netherlands and is therefore compensated in the local currency, i.e. Euro's. Dr. Bruinsma's salary for 2004 was Euro 300,000 and his expense allowance was Euro 25,000. These amounts are reflected in the table above at the average dollar/euro exchange rate of 1.24 for 2004, 1.13 for 2003, and 0.95 for 2002. Dr. Bruinsma was appointed Chief Executive Officer on March 3, 2005.
- (2) S. Colin Neill became an employee of Axonyx in September 2003. Mr. Neill was reimbursed \$10,000 for various business expenses including life insurance.

- (3) No Named Executive Officer was paid other annual compensation in an amount exceeding the lesser of either \$50,000 or 10% of the total annual salary and bonus for the Named Executive Officer.
- (4) The number of options granted for certain Executive Officers in 2003 have been adjusted to include options granted in 2003 under our 2000 Stock Option Plan which were contingent upon the January 1, 2004 increase in the number of shares reserved for issuance under the 2000 Stock Option Plan by 750,000 shares per the evergreen provision. The increase in options granted for each Executive Officer in 2003 due to this adjustment are as follows: Marvin S. Hausman, M.D. 125,000; Gosse B. Bruinsma, M.D. 100,000; S. Colin Neill 93,620.
- (5) The Company reimbursed the Chairman and CEO to cover costs of maintaining an office and related support costs in Portland, Oregon. Dr. Hausman stepped down as Chief Executive Officer effective March 3, 2005 but remains Chairman of the Board.

B. Option Grants in Fiscal Year 2004

The following table sets forth certain information with respect to option grants to our Named Executive Officers in 2004. All of the grants were made under the Axonyx 2000 Stock Option Plan. We have not granted any stock appreciation rights.

Option Grants in Fiscal Year 2004						
Name	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term (1)	
	Number of securities underlying Options Granted (#)	Percent of total options granted to employees in fiscal year	Exercise or base price (\$/Sh)	Expiration date	5% (\$)	10% (\$)
Marvin S. Hausman (2)	200,000	57.1%	\$7.03	12/7/14	\$884,226	\$2,240,802
Gosse B. Bruinsma (3)	100,000	28.6%	\$7.03	12/7/14	\$442,113	\$1,120,401
S. Colin Neill (4)	50,000	14.3%	\$7.03	12/7/14	\$221,056	\$ 560,200

- (1) These amounts represent hypothetical gains that could be achieved for the respective options at the end of the ten year option term. The assumed 5% and 10% rates of compounded stock price appreciation are mandated by rules of the Securities and Exchange Commission and do not represent Axonyx's estimate of the future market price of the common stock.
- (2) On December 7, 2004, Axonyx granted 200,000 Incentive Stock Options exercisable at \$7.03 per share to Marvin S. Hausman, M.D., with 50,000 options vesting on December 7, 2004, 2005, 2006 and 2007.
- (3) On December 7, 2004, Axonyx granted 100,000 Incentive Stock Options exercisable at \$7.03 per share to Gosse B. Bruinsma, M.D., with 25,000 options vesting on December 7, 2004, 2005, 2006 and 2007.
- (4) On December 7, 2004 Axonyx granted 50,000 Incentive Stock Options exercisable at \$7.03 per share to S. Colin Neill, with 12,500 options vesting on December 7, 2004, 2005, 2006 and 2007.

C. Aggregate Option Exercises in Fiscal Year 2004 Year End Option Values

The following table sets forth the number and value of unexercised options held by the Named Executive Officers as of December 31, 2004.

Aggregated Option Exercises in Fiscal Year 2004 and Year-End Option Values

Name	Number of shares acquired on exercise	Value (\$) Realized	Number of securities underlying unexercised options at fiscal year end #(1)	Value of unexercised in-the-money options at fiscal year end (\$) (2)
			Exercisable/unexercisable	Exercisable/unexercisable
Marvin S. Hausman, M.D., Chairman & CEO	175,000	\$ 845,000	562,500/ 362,500	\$769,875/ \$815,875
Gosse B. Bruinsma, M.D., Pres. & COO	215,000	\$1,064,000	435,000/ 290,000	\$699,900/ \$846,850
S. Colin Neill, C.F.O.	—	—	117,500/ 142,500	\$256,950/ \$256,950
Robert G. Burford, V.P.	—	—	224,000/ 0	\$206,000/ \$ 0
Michael R. Espey, V.P. & Secretary	89,000	\$ 435,000	0/ 0	\$ 0/ \$ 0

- (1) The number of options granted for certain Executive Officers in 2003 have been adjusted to include options granted in 2003 under our 2000 Stock Option Plan which were contingent upon the January 1, 2004 increase in the number of shares reserved for issuance under the 2000 Stock Option Plan by 750,000 shares per the evergreen provision. The increase in options granted for each Executive Officer in 2003 due to this adjustment are as follows: Marvin S. Hausman, M.D. 125,000; Gosse B. Bruinsma, M.D. 100,000; S. Colin Neill 93,620.
- (2) Dollar amounts reflect the net values of outstanding stock options computed as the difference between \$6.20 (the fair market value at December 31, 2004) and the exercise price of the options.
- (3) Dr. Bruinsma replaced Dr. Hausman as CEO effective March 3, 2005.

D. Compensation to Directors

In December of 2004 the Company adopted the following policy to compensate outside directors:

The chairman of the audit committee and the scientific advisory committee each receives compensation of \$25,000 annually. The chairman of the compensation committee and the nominating committee each receives compensation of \$15,000 annually. Directors will also receive \$2,500 for each board or committee meeting they attend either in person or by telephone if the duration of the meeting exceeds 2 hours. Directors will receive \$1,000 for each board or committee meeting they attend by telephone if the duration of the meeting is less than 2 hours. In addition, we have agreed to reimburse our directors for reasonable expenses incurred in attending meetings of the board of directors and its committees.

Outside directors may be granted stock options on a discretionary basis. In 2004 Dr. Steven Ferris, Dr. Gerard Vlak and Mr. Louis Cornacchia received 50,000 stock options each. Mr. Michael Griffith received 100,000 stock options. Dr. Snyderman received 150,000 stock options.

E. Employment Contracts with Executive Officers and Termination of Employment and Change-in-Control Arrangements

Axonyx does not have employment contracts with any of its Named Executive Officers, except as follows:

Gosse B. Bruinsma, M.D., President, Chief Operating Officer and Director. On September 21, 2002 Axonyx signed an Employment Agreement with Dr. Bruinsma under which Dr. Bruinsma agreed to serve as President of Axonyx Europe BV, a wholly owned subsidiary of Axonyx Inc, and Chief Operating Officer of Axonyx Inc. This agreement has been renewed and now extends through September 2006. The salary has been determined at Euro 330,000 and the expense reimbursement at Euro 25,000, including for the use of a home office and personal equipment, health insurance, disability insurance, life insurance, pension distribution and auto lease premium.

In March 2004, following approval of the Compensation Committee and the Board, Axonyx entered into change of control agreements with Marvin S. Hausman, Gosse Bruinsma and S. Colin Neill. Each agreement provides that if the executive's employment is terminated without "cause," as defined in the agreement, within 90 days prior to, or one year following, a "change of control," he will receive severance pay equal to 200% of his annual base salary for the then-current year, plus the greater of the annual bonus he received for the prior year or the then-current annual target bonus. Such payments are also required to be made in connection with a change of control if the executive has "good reason" to terminate his employment, as defined in the agreement. A "change of control" involves an acquisition of at least 50% of the voting power of the Company's securities, a change in at least a majority of the members of the current Board of Directors, or approval by the Board of Directors or stockholders of the Company of a transaction where such change of voting control or composition of the Board would occur, where the Company would be liquidated or where all or substantially all of its assets would be sold.

In addition, all options granted under the 1998 Stock Option Plan and the 2000 Stock Option Plan, including those to its executive officers, provide for accelerated vesting upon a change in control, among other events.

F: Compensation Committee Interlocks and Insider Participation

The members of the Compensation Committee during 2004 were Dr. Steven Ferris, Dr. Gerard Vlak, Mr. Louis Cornacchia and Mr. Michael Griffith, who joined the Compensation Committee in November 2004. None of the members of the Compensation Committee has ever been an officer or employee of Axonyx or any subsidiary, nor have they had a relationship with Axonyx requiring disclosure under the applicable rules of the SEC.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information regarding beneficial ownership of our common stock as of February 28, 2005, unless otherwise indicated, (a) by each person known by us to own beneficially 5% or more of any class of our common stock, (b) by each of our Named Executive Officers and directors and (c) by all executive officers and directors of Axonyx as a group. As of February 28, 2005 there were 53,665,518 shares of our common stock issued and outstanding. The numbers of shares beneficially owned include shares of common stock that the listed beneficial owners have the right to acquire within 60 days of February 28, 2005 upon the exercise of all options and other rights beneficially owned on that date. Unless otherwise noted, we believe that all persons named in the table have sole voting and investment power with respect to all the shares beneficially owned by them.

<u>Name of Beneficial Owner (1)</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percent of Class</u>
Marvin S. Hausman, M.D. (2)	3,002,439	5.25%
Gosse B. Bruinsma, M.D. (3)	485,500	0.90%
S. Colin Neill (4)	117,500	0.22%
Louis G. Cornacchia (5)	263,933	0.49%
Steven H. Ferris, Ph.D. (6)	79,000	0.15%
Gerard J. Vlask, Ph.D. (7)	102,500	0.19%
Ralph Snyderman, M.D. (8)	62,500	0.12%
Michael Griffith (9)	52,000	0.10%
All directors and executive officers (8 persons) as a group	4,165,372	7.54%
HYMF Limited (10)	3,092,630	5.76%
Kilkenny Capital Management, LLC (11)	2,818,735	5.25%

- (1) Unless otherwise indicated, the address of each of the listed beneficial owners identified above is c/o 500 Seventh Avenue, 10th Floor, New York, NY 10018.
- (2) Marvin S. Hausman, M.D. Includes: (i) 2,389,939 shares owned by Dr. Hausman; (ii) 100,000 vested but unexercised options exercisable at \$11.50 per share granted on January 10, 2000, (iii) 150,000 vested but unexercised options exercisable at \$7.91 per share granted on December 15, 2000, and (iv) 200,000 vested but unexercised options exercisable at \$3.16 per share granted on December 11, 2001, (v) 62,500 vested but unexercised options exercisable at \$ 3.61 per share granted on November 18, 2003. This grant was contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, (vi) 50,000 vested but unexercised options exercisable at \$7.03 per share granted on December 7, 2004, and (vii) 50,000 unvested options exercisable at \$1.18 per share granted on March 17, 2003 that will vest within 60 days. Does not include: (i) 3,000 shares gifted to Dr. Hausman's three adult children, with 1,000 to each in October 1999, (ii) 200 shares gifted to Roberta Matta in October 1999, (iii) 5,000 shares gifted to a religious institution in October 2000, (iv) 5,000 shares gifted to six non-affiliate donees in September 2000, (v) 10,550 shares gifted to six non-affiliate donees, including Dr. Hausman's three adult children in July 2001, (vi) 4,300 shares gifted to three non-affiliate donees in October 2001, (vii) 3,000 shares gifted to a non-affiliate donee in October 2001, (viii) 12,300 shares gifted to Dr. Hausman's three adult children and Roberta Matta in December 2001, (ix) 4,717 shares gifted to two non-affiliate donees in December 2001, (x) 8,834 shares gifted to five non-affiliate donees in February 2002, (xi) 4,500 shares gifted to two non-affiliate donees in March 2002, (xii) 5,832 shares gifted to five non-affiliate donees, (xiii) 16,000 shares gifted to three non-affiliate donees in September 2002, (xiv) 20,000 shares gifted to two non-affiliate donees in February 2003, (xv) 10,000 shares gifted to a non-affiliate donee in March 2003, (xvi) 60,000 shares gifted to an non-affiliated donee in April 2003, and (xvii) 1,000 shares gifted to Roberta Matta in April 2003, and (xviii) 2000 share gifted to a non-affiliated donee, 500 shares gifted to Kevin Matta and 1,000 shares gifted to Roberta Matta in February 2004, (xix) 4,000 shares gifted to two non-affiliated donees in June 2004, (xx) 7,500 shares gifted to three adult children in August 2004, (xxi) 16,350 shares gifted to ten non-affiliated donees in August 2004, (xxii) 180 shares gifted to non-affiliated donees and 50 shares gifted to a family member in October 2004, (xxiii) 1000 shares gifted to Roberta Matta in December 2004, (xxix) 1000 shares gifted to four family members in December 2004, (xv) 50,000 unvested options exercisable at \$3.16 per share granted on December 11, 2001,

- (xxv) 50,000 unvested options exercisable at \$1.18 granted on March 17, 2003, and (xxvii) 62,500 unvested options exercisable at \$3.61 per share granted on November 18, 2003. This grant was contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, and (xxviii) 150,000 unvested options exercisable at \$7.03 per share granted on December 7, 2004.
- (3) Gosse B. Bruinsma, M.D. Includes: (i) 500 shares owned by Gosse Bruinsma, M.D., (ii) 150,000 vested but unexercised options exercisable at \$9.50 per share granted on October 10, 2000; (iii) 50,000 vested but unexercised options exercisable at \$4.52 per share granted on May 11, 2001; (iv) 160,000 vested but unexercised options exercisable at \$3.16 per share granted on December 11, 2001; (v) 50,000 vested but unexercised options exercisable at \$3.61 per share granted November 18, 2003. This grant was contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, (vi) 25,000 vested but unexercised options exercisable at \$7.03 per share granted December 7, 2004; (vii) 50,000 unvested options exercisable at \$1.07 per share granted on March 17, 2003 that will vest within 60 days. Does not include: (i) 40,000 unvested options exercisable at \$3.16 per share granted on December 11, 2001; (ii) 25,000 unvested options exercisable at \$2.89 per share granted on June 11, 2002; (iii) 50,000 unvested options exercisable at \$1.07 per share granted on March 17, 2003; (iv) 50,000 unvested options exercisable at \$3.61 per share granted November 18, 2003. This grant was contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, and (vii) 75,000 unvested options exercisable at \$7.03 per share granted December 7, 2004.
- (4) S. Colin Neill. Includes: (i) 100,000 vested but unexercised options exercisable at \$3.76 granted on September 15, 2003, of which 23,405 options were contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, (ii) 5,000 vested but unexercised option exercisable at \$3.61 granted on November 18, 2003, and (iii) 12,500 vested but unexercised options exercisable at \$7.03 per share granted December 7, 2004. Does not include: (i) 100,000 unvested options exercisable at \$3.76 per share granted on September 15, 2003, of which 70,215 options were contingent upon the 2000 stock option plans evergreen provision effective January 1, 2004, (ii) 5,000 unvested options exercisable at \$3.61 per share granted on November 18, 2003, and (iii) 37,500 unvested options exercisable at \$7.03 per share granted December 7, 2004.
- (5) Louis G. Cornacchia. Includes: (i) 138,622 shares owned by Mr. Cornacchia; (ii) 33,311 common stock purchase warrants exercisable at \$0.688 per share purchased in a private placement on December 31, 2002; (iii) 2,000 common stock purchase warrants exercisable at \$11.00 per shares purchased in a private placement on October 25, 1999; (iv) 30,000 vested but unexercised options exercisable at \$0.825 per share granted on February 21, 2003 (v) 25,000 vested but unexercised options exercisable at \$4.24 per share granted September 23, 2003 (vi) 25,000 vested but unexercised options exercisable at \$5.27 per share granted October 12, 2004, and (vii) 10,000 unvested options exercisable at \$0.825 per share granted on February 21, 2003 that will vest in the next sixty days. Does not include: (i) 10,000 unvested options exercisable at \$0.825 per share granted on February 21, 2003 (ii) 25,000 unvested options exercisable at \$4.24 per share granted September 23, 2003, and (iii) 25,000 unvested options exercisable at \$5.27 per share granted October 12, 2004.
- (6) Steven H. Ferris, Ph.D. Includes: (i) 5,000 vested but unexercised options exercisable at \$7.00 per share granted on March 25, 2000; (ii) 4,000 vested but unexercised options exercisable at \$11.00 per share granted on March 25, 2000 (iii) 10,000 vested but unexercised options exercisable at \$3.06 per share granted on February 15, 2002, (iv) 10,000 vested but unexercised options exercisable at \$1.11 per share granted on January 14, 2003 (v) 25,000 vested but unexercised options exercisable at \$4.24 per share granted September 23, 2003 and (vi) 25,000 vested but unexercised options exercisable at \$5.27 per share granted October 12, 2004. Does not include: (i) 10,000 unvested options exercisable at \$1.11 per share granted on January 14, 2003 and (ii) 25,000 unvested options exercisable at \$4.24 per share granted September 23, 2003 and (iii) 25,000 unvested options exercisable at \$5.27 per share granted October 12, 2004.
- (7) Gerard J. Vlak, Ph.D. Includes: (i) 30,000 vested but unexercised options exercisable at \$0.825 per share granted on February 21, 2003 (ii) 27,500 vested but unexercised options exercisable at \$4.24 per share granted September 23, 2003, (iii) 25,000 vested but unexercised options exercisable at \$5.27 per share granted October 12, 2004, and (iv) 10,000 unvested options exercisable at \$0.825 per share granted on February 21, 2003 that will vest in the next 60 days.. Does not include: (i) 20,000 unvested options exercisable at \$0.825 per share granted on February 21, 2003 (ii) 37,500 unvested options exercisable at \$4.24 per share granted September 23, 2003, and (iii) 25,000 unvested options exercisable at \$5.27 per share granted October 12, 2004.

- (8) Ralph Snyderman, M.D. Includes: (i) 12,500 vested but unexercised options exercised at \$7.09 per share granted on March 8, 2004. (ii) 25,000 vested but unexercised options exercisable at \$5.27 per share granted October 12, 2004 (iii) 12,500 unvested options exercisable at \$7.09 per share granted on March 8, 2004 that will vest within sixty days, and (iv) 12,500 vested but unexercised options exercisable at \$7.03 per share granted December 7, 2004. Does not include: (i) 25,000 unvested options exercisable at \$7.09 per share granted on March 8, 2004 (ii) 25,000 unvested options exercisable at \$5.27 per share granted October 12, 2004, and (iii) 37,500 unvested options exercisable at \$7.03 per share granted December 7, 2004.
- (9) Michael Griffith. Includes: (i) 2,000 shares owned by Mr. Griffith; (ii) 50,000 vested but unexercised options exercisable at \$5.27 per share granted on October 12, 2004; Does not include: (i) 50,000 unvested options exercisable at \$5.27 per share granted on October 12, 2004.
- (10) HYMF Limited, Walker House Mary Street PO Box 908 GT, George Town, Grand Cayman. This information is based on a Schedule 13G filed by the holder on February 14, 2005, and is as of December 31, 2004. HYMF Limited holds the shares in trust accounts for the economic benefit of the beneficiaries of those accounts. HYMF Limited has sole power to direct the vote of 2,629,791 of the shares, and sole power to dispose or to direct the disposition of 3,092,630 shares.
- (11) Kilkenny Capital Management, LLC, 311 South Wacker Drive, Suite 6350, Chicago, IL 60606. This information is based on a Schedule 13G filed by the holder on February 14, 2005, and is as of December 31, 2004. Kilkenny Capital Management, LLC, is a registered investment advisor, and, together with its controlling members, Michael P. Walsh and Elizabeth R. Foster, has shared voting power and shared dispositive power over the 2,818,735 shares.

Equity Compensation Plan Information

The following table sets forth information about the common stock available for issuance under compensatory plans and arrangements as of December 31, 2004.

<u>Plan Category</u>	<u>(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>(b) Weighted-average exercise price of outstanding options, warrants, and rights</u>	<u>(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
Equity compensation plan approved by security holders (1)	983,600	\$5.96	—
Equity compensation plan approved by security holders (2)	3,450,500	\$4.21	3,392,380
Equity compensation plans not approved by security holders	<u>342,500(3)</u>	<u>\$4.51</u>	—
Total	<u>4,776,600</u>	<u>\$4.60</u>	<u>3,392,380</u>

- (1) As of February 28, 2005, we have granted options to purchase an aggregate of 983,600 shares of common stock under our 1998 Stock Option Plan. As of December 31, 2004, no options are available for future grant under the 1998 plan. The plan terminated on January 15, 2003.
- (2) As of February 28, 2005, we have granted options to purchase an aggregate of 3,450,500 shares of common stock under our 2000 Stock Option Plan. The number of shares reserved for issuance pursuant to options under the 2000 Stock Option Plan, as amended on June 14, 2002, was increased by 750,000 shares on January 1, 2003 pursuant to an evergreen provision in the stock option plan. 318,620 options in 2003 were issued contingent upon the January 1, 2004 evergreen provision that will increase the stock option plan shares by 750,000 shares. On March 30, 2004, the Company amended the 2000 Plan to increase the aggregate number of shares from 3,500,000 to 7,500,000. Stockholder approval for the increase was received in June 2004.
- (3) We have granted an aggregate of 342,500 options to consultants and advisors outside of our 1998 and 2000 stock option plans.

Item 13. Certain Relationships and Related Transactions

The Company reimburses the Chairman for certain costs incurred in maintaining an office and related support in Portland, Oregon. The amounts in 2004 and 2003 were \$54,000 and \$32,000 respectively.

Item 14. Principal Accountant Fees and Services

AUDIT FEES

Aggregate fees billed for professional services rendered by Eisner LLP in connection with its audit of the Company's consolidated financial statements as of and for the years ended December 31, 2004, and 2003, its reviews of the Company's unaudited condensed consolidated interim financial statements, and for SEC consultations and filings were \$153,000 and \$75,000, respectively.

AUDIT-RELATED FEES

The audit-related fees billed for professional services rendered by Eisner LLP for the years ended December 31, 2004, and 2003 were \$26,500 and \$1,400, respectively. These fees were primarily for Sarbanes-Oxley compliance.

TAX FEES

Aggregate fees billed for professional services rendered by Eisner LLP in connection with its income tax compliance and related tax services for the years ended December 31, 2004, and 2003 were \$11,000 and \$14,000, respectively. These tax fees included (1) tax return preparation fee, (2) New York City desk audit and amended return and (3) assistance with the filing of a withdrawal from Connecticut.

ALL OTHER FEES

There were no other professional services rendered to us by Eisner LLP in 2004 or 2003.

PRE-APPROVAL POLICY

The charter of the audit committee requires that the committee pre-approve all auditing services and permitted non-audit services (including the fees and terms thereof) to be performed for the company by its independent auditor, subject to any exception permitted by law or regulation. The Audit Committee pre-approved all auditing services and permitted non-audit services rendered by Eisner LLP in 2004.

Item 15. Exhibits and Financial Statement Schedules

Consolidated Financial Statements:

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Exhibits:

- 2.1 Agreement of Merger between Axonyx Inc. and Ionosphere, Inc. dated December 23, 1998 (Incorporated by reference to the corresponding exhibit to the Registration Statement on Form 10-SB previously filed by Axonyx on March 17, 1999 (File No. 000-25571) (the "March 17, 1999 10-SB"))
- 2.2 Articles of Merger (Delaware) dated December 28, 1998 and Certificate of Correction dated March 10, 1999 (Incorporated by reference to the corresponding exhibit to the March 17, 1999 10-SB)
- 2.3 Articles of Merger (Nevada) dated December 28, 1998 (Incorporated by reference to the corresponding exhibit to the March 17, 1999 10-SB)
- 3.1 Restated Articles of Incorporation dated June 23, 2000 (Incorporated by reference to exhibit number 3.0(i) to the Quarterly Report on Form 10-QSB previously filed by Axonyx on August 14, 2000)
- 3.2 By-Laws (Incorporated by reference to the corresponding exhibit to the March 17, 1999 10-SB)
- 3.3 Certificate of Amendment of Restated Articles of Incorporation dated June 28, 2004 (incorporated by reference to Exhibit 3(a) in the quarterly report on Form 10-Q previously filed by Axonyx Inc. for the quarter ended June 30, 2004)
- 4.1 Form of Common Stock Purchase Warrant AXB (Incorporated by reference to exhibit 4.3 to the Annual Report on Form 10-KSB previously filed by Axonyx on March 13, 2000 (the "March 13, 2000 10-KSB"))
- 4.2 Form of Registration Rights Agreement 1999 (Incorporated by reference to exhibit 4.4 to the March 13, 2000 10-KSB)
- 4.3 Form of Warrant (Stonegate Securities) (Incorporated by reference to the corresponding exhibit to the Annual Report on Form 10-KSB previously filed by Axonyx on March 22, 2001 (the "March 22, 2001 10-KSB"))
- 4.4 Form of Common Stock Purchase Warrant AXC (Incorporated by reference to exhibit 10.2 to the Current Report on Form 8-K previously filed by Axonyx on December 13, 2001 (the "December 13, 2001 8-K"))
- 4.5 Form of Warrant (SCO Financial Group) (Incorporated by reference to the corresponding exhibit to the Registration Statement on Form S-3 previously filed by Axonyx on January 3, 2002 (File No. 333-76234))
- 4.6 Form of Common Stock Purchase Warrant [AXD](Incorporated by reference to Exhibit 10.2 in the Form 8-K previously filed by Axonyx on January 8, 2003 (File no. 00025571))
- 4.8 Form of Warrant (AFO Advisors, LLC) (Incorporated by reference to Exhibit 4.2 in the registration statement on Form S-3 previously filed by Axonyx on February 12, 2003 (File No. 333-103130))
- 4.9 Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 10.2 in the current report on Form 8-K previously filed by Axonyx on September 16, 2004 (File No. 00025571))
- 4.10 Form of Warrant (Incorporated by reference to Exhibit 4.3 in the current report on Form 8-K previously filed by Axonyx on January 12, 2004 (File No. 00025571))
- 4.11 Registration Rights Agreement dated as of January 8, 2004 between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.2 in the current report on Form 8-K previously filed by Axonyx Inc. on January 12, 2004)
- 4.12 Registration Rights Agreement dated as of May 3, 2004, between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.2 in the current report on Form 8-K previously filed by Axonyx Inc. on May 5, 2004)

- 10.1 1998 Stock Option Plan (Incorporated by reference to the corresponding exhibit to the March 17, 1999 10-SB)
- 10.2(a) 2000 Stock Option Plan (Incorporated by reference to exhibit 99.2 to the Registration on Form S-8 previously filed by Axonyx on October 17, 2000 (file number 333-48088))
- 10.2(b) First Amendment to 2000 Stock Option Plan (Incorporated by reference to the corresponding exhibit to Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.2(c) Second Amended and Restated 2000 Stock Option Plan (Incorporated by reference to Appendix E to Schedule 14A previously filed by the Company on May 14, 2004)
- 10.3(a) Patent License Agreement — Exclusive between the Public Health Service and CURE, LLC dated January 31, 1997 (Incorporated by reference to exhibit 10.2 to the Registration Statement on Form 10-SB Amendment No. 1 previously filed by Axonyx on August 10, 1999 (File no. 000-25571) (the “August 10, 1999 10-SB/A”))
- 10.3(b) License Agreement between the Axonyx Inc. and CURE, LLC dated February 27, 1997 (Incorporated by reference to exhibit 10.2 to the March 17, 1999 10-SB)
- 10.3(c) Letter Amendment of License Agreement between Axonyx Inc. and CURE, LLC dated May 27, 2002 (Incorporated by reference to exhibit 10.1 to Form 10-Q previously filed on August 14, 2002 (File No. 000-25571))
- 10.4 Research and License Agreement between the Axonyx Inc. and New York University dated April 1, 1997 (Incorporated by reference to exhibit 10.3 to the March 17, 1999 10-SB)
- 10.5 Second Amendment to Research and License Agreement between Axonyx Inc. and New York University dated March 19, 1999 (Incorporated by reference to exhibit A to the Quarterly Report on Form 10-Q previously filed by Axonyx on June 30, 1999)
- 10.6 Fourth Amendment to Research and License Agreement between Axonyx Inc. and New York University dated October 11, 2002 (Incorporated by reference to exhibit 10.1 to Form 10-Q previously filed on November 14, 2002 (File No. 000-25571))
- 10.7 Financial Consulting Agreement between Axonyx Inc. and Intertrend Management, Ltd. dated November 6, 1998 (Incorporated by reference to exhibit 10.7 in the August 10, 1999 10-SB/A)
- 10.8 Development Agreement and Right to License between Axonyx Inc. and Applied Research Systems ARS Holding N.V. dated May 17, 1999 (Incorporated by reference to exhibit 99(c) to the Current Report on Form 8-K previously filed by Axonyx on June 1, 1999)
- 10.9 License Agreement between Axonyx Inc. and Applied Research Systems ARS N.V. dated September 15, 2000 (Incorporated by reference to exhibit 10.9 to the March 22, 2001 10-KSB)
- 10.10 Sponsored Research Agreement between the University of Melbourne and Axonyx Inc. dated October 1, 1999 (Incorporated by reference to exhibit 10.10 to the March 22, 2001 10-KSB)
- 10.11 Common Stock Underwriting Agreement between Ramius Securities, LLC and Axonyx Inc. dated October 25, 2000 (Incorporated by reference to exhibit 10.11 to the March 22, 2001 10-KSB)
- 10.12 Stand-By Purchase Agreement between Ramius Capital Group, LLC and Axonyx Inc. dated October 25, 2000 (Incorporated by reference to exhibit 10.12 to the March 22, 2001 10-KSB)
- 10.13 Lease Agreement between Axonyx Inc. and Business Service Center of Seattle dated January 28, 1999 (Incorporated by reference to exhibit 10.5 to the March 17, 1999 10-SB)
- 10.14 Occupancy Agreement between Axonyx Inc., J.A. Bernstein & Co. and The Garnet Group, Inc. dated December 14, 1999 (Incorporated by reference to exhibit 10.10 to the March 13, 2000 10-KSB)

- 10.15 Letter Agreement between Axonyx Inc. and J.A. Bernstein & Co. dated December 9, 1999 (Incorporated by reference to exhibit 10.11 to the March 13, 2000 10-KSB)
- 10.16 Data Management and Reporting Services Agreement between Axonyx Inc. and Clinfo Systems, LLC dated October 2, 2000 (Incorporated by reference to the corresponding exhibit to the Annual Report on Form 10-KSB Amendment No. 1 previously filed by Axonyx on May 15, 2001 (the "May 15, 2001 10-KSB/A"))
- 10.17 Data Management and Reporting Services Agreement between Axonyx Inc. and Clinfo Systems, LLC dated January 2, 2001 (Incorporated by reference to the corresponding exhibit to the May 15, 2001 10-KSB/A)
- 10.18† Research Agreement between Thomas Jefferson University and Axonyx Inc. dated as of April 1, 2001 (Incorporated by reference to exhibit 10.1 to the Quarterly Report on Form 10-Q previously filed by Axonyx on May 15, 2001)
- 10.19 Sponsored Research Agreement and Option between Mayo Foundation for Medical Education and Research, Mayo Clinic Jacksonville and Axonyx Inc. dated May 1, 2001 (Incorporated by reference to the corresponding exhibit to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.20 Research Agreement between Indiana University and Axonyx Inc. dated August 15, 2001 (Incorporated by reference to the corresponding exhibit to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.21 Common Stock and Warrant Purchase Agreement dated December 4, 2001 (Incorporated by reference to exhibit 10.1 to the December 13, 2001 8-K)
- 10.22** Employment Agreement by and between Axonyx Europe B.V. and Dr. Gosse Bruinsma dated October 10, 2000 (Incorporated by reference to exhibit 10.22 to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.23** Letter Agreement between Axonyx Inc. and Dr. Robert Burford dated November 10, 1999 (Incorporated by reference to exhibit 10.23 to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.24 Research Agreement between David Henry Small, Ph.D. and Axonyx Inc. dated September 1, 2002 (Incorporated by reference to exhibit 10.2 to Form 10-Q previously filed on November 14, 2002 (File No. 000-25571))
- 10.25 Intellectual Property Assignment Agreement between David Henry Small, Ph.D., Marie-Isabel Aguilar, Ph.D., Supundi Subasinghe and Axonyx Inc. dated September 1, 2002 (Incorporated by reference to exhibit 10.3 to Form 10-Q previously filed on November 14, 2002 (File No. 000-25571))
- 10.26 Common Stock and Warrant Purchase Agreement dated as of December 31, 2002 (Incorporated by reference to Exhibit 10.1 in the Form 8-K previously filed by Axonyx on January 8, 2003 (File No. 00025571))
- 10.27 Clinical Trial Services Master Agreement between JSW Research and Axonyx Inc. dated March 21, 2003 (Incorporated by reference to Exhibit 10.27 in the Form 10-K previously filed by Axonyx on March 31, 2003 (File No. 00025571))
- 10.28 Contract between Axonyx Europe and NOTOX Safety and Environmental Research B.V. dated April 11, 2002 (Incorporated by reference to Exhibit 10.28 in the Form 10-K previously filed by Axonyx on March 31, 2003 (File No. 00025571))
- 10.29 Common Stock and Warrant Purchase Agreement dated as of September 11, 2003 (Incorporated by reference to Exhibit 10.1 in the current report on Form 8-K previously filed by Axonyx on September 16, 2004 (File No. 00025571))
- 10.30 Securities Purchase Agreement dated as of January 8, 2004 (Incorporated by reference to Exhibit 4.1 in the current report on Form 8-K previously filed by Axonyx on January 12, 2004 (File No. 00025571))

- 10.31 Share Exchange Agreement dated as of January 15, 2004 between Axonyx Inc. and Oxis International, Inc., (incorporated by reference to Exhibit 10.1 in the current report on Form 8-K previously filed by Axonyx Inc. on January 20, 2004)
- 10.32** Change of Control Agreement dated as of March 30, 2004 between Axonyx and Marvin S. Hausman (incorporated by reference to Exhibit 10.32 of Axonyx Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2003)
- 10.33** Change of Control Agreement dated as of March 30, 2004 between Axonyx and Gosse Bruinsma (incorporated by reference to Exhibit 10.33 of Axonyx Inc. Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2003)
- 10.34** Change of Control Agreement dated as of March 30, 2004 between Axonyx and S. Colin Neill (incorporated by reference to Exhibit 10.34 of Axonyx Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2003)
- 10.35 Securities Purchase Agreement dated as of May 3, 2004 between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.1 in the current report on Form 8-K previously filed by Axonyx Inc. on May 5, 2004)
- 14 Code of Business Conduct and Ethics*
- 21 List of Subsidiaries (Incorporated by reference to the corresponding exhibit to the March 22, 2001 10-KSB)
- 23.1 Consent of Eisner LLP*
- 31.1 Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer*
- 31.2 Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer*
- 32 Section 1350 Certification of Chief Executive Officer and Chief Financial Officer*

* Filed herewith

** Indicates management compensation agreement

† Certain information omitted pursuant to a request for confidential treatment filed separately with and granted by the SEC

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act of 1934, as amended, the registrant caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, New York on this 16th day of March, 2005.

AXONYX INC.

By: /s/ Gosse B. Bruinsma, M.D.

Gosse B. Bruinsma, M.D.
Chief Executive Officer

In accordance with Section 13 or 15(d) of the Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant in the capacities indicated below on this 16th of March, 2005.

<u>Signature</u>	<u>Title</u>
<u>/s/ Gosse B. Bruinsma, M.D.</u> Gosse B. Bruinsma, M.D.	Chief Executive Officer, (Principal Executive Officer)
<u>/s/ Marvin S. Hausman, M.D.</u> Marvin S. Hausman, M.D.	Director and Chairman
<u>/s/ S. Colin Neill</u> S. Colin Neill	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)
<u>/s/ Louis G. Cornacchia</u> Louis G. Cornacchia	Director
<u>/s/ Steven H. Ferris, Ph.D.</u> Steven H. Ferris, Ph.D.	Director
<u>Michael A. Griffith</u>	Director
<u>Ralph Snyderman, MD</u>	Director
<u>/s/ Gerard J. Vlak, Ph.D.</u> Gerard J. Vlak, Ph.D.	Director

AXONYX INC.
CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2004 and 2003

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AXONYX INC.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Axonyx Inc.

We have audited the accompanying consolidated balance sheets of Axonyx Inc. and subsidiaries as of December 31, 2004 and 2003 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2004. 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 audits.

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

In our opinion, the financial statements enumerated above present fairly, in all material respects, the consolidated financial position of Axonyx Inc. and subsidiaries as of December 31, 2004 and 2003, and the consolidated results of their operations and their consolidated cash flows for each of the years in the three-year period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

EISNER LLP

New York, New York
March 9, 2005
With respect to Notes A and J[5]
March 11, 2005

AXONYX INC.
Consolidated Balance Sheets

	December 31,	
	2004	2003
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 90,591,000	\$ 28,780,000
Accounts receivable	229,000	
Stock subscriptions receivable	2,250,000	
Inventories	246,000	
Other current assets	141,000	
Total current assets	93,457,000	28,780,000
Property, plant and equipment, net	116,000	24,000
Technology for developed products, net	6,807,000	
Patents and patents pending, net	995,000	
Security deposits	19,000	11,000
	\$101,394,000	\$ 28,815,000
LIABILITIES		
Current liabilities:		
Accounts payable	\$ 6,365,000	\$ 1,284,000
Accrued expenses	2,386,000	880,000
Note payable	160,000	
Total current liabilities	8,911,000	2,164,000
Outside interest in OXIS	5,945,000	
STOCKHOLDERS' EQUITY		
Preferred stock — \$.001 par value, 15,000,000 shares authorized; none issued		
Common stock — \$.001 par value, 150,000,000 and 75,000,000 shares authorized; as of 2004 and 2003 respectively; 53,645,518 and 33,919,948 shares issued and outstanding in 2004 and 2003 respectively	54,000	34,000
Additional paid-in capital	149,150,000	60,345,000
Unearned compensation — stock options	(144,000)	
Accumulated comprehensive loss	(14,000)	
Accumulated deficit	(62,508,000)	(33,728,000)
Total stockholders' equity	86,538,000	26,651,000
Total liabilities and stockholders' equity	\$101,394,000	\$ 28,815,000

See notes to consolidated financial statements

AXONYX INC.

Consolidated Statements of Operations

	Year Ended December 31,		
	2004	2003	2002
Revenue			
Licensing	\$ 450,000	\$ 1,000,000	
Product sales	<u>1,825,000</u>		
Total revenue	2,275,000	1,000,000	
Cost of product sales	<u>(1,167,000)</u>		
	1,108,000	1,000,000	
Costs and expenses:			
Research and development	23,741,000	5,821,000	\$ 3,852,000
Sales, general and administrative	<u>8,250,000</u>	<u>3,459,000</u>	<u>2,505,000</u>
	<u>31,991,000</u>	9,280,000	6,357,000
Loss from operations	<u>(30,883,000)</u>	(8,280,000)	(6,357,000)
Other income (expenses)			
Interest income	1,235,000	137,000	101,000
Foreign exchange	(83,000)	37,000	
Gain on issuance of subsidiary stock	1,154,000		
Other income	19,000		
Financing fees	(856,000)		
Interest expense	<u>(51,000)</u>		
Net loss before minority interest in subsidiary	<u>(29,465,000)</u>	(8,106,000)	(6,256,000)
Minority interest in loss of subsidiary	<u>685,000</u>		
Net loss	<u>(28,780,000)</u>	(8,106,000)	(6,256,000)
Comprehensive loss			
Foreign currency translation adjustment	<u>(14,000)</u>		
Comprehensive loss	<u>\$(28,794,000)</u>	<u>\$(8,106,000)</u>	<u>\$(6,256,000)</u>
Net loss per common share	<u>\$ (.58)</u>	<u>\$ (.30)</u>	<u>\$ (.36)</u>
Weighted average shares — basic and diluted	49,977,000	27,207,000	17,265,000

See notes to consolidated financial statements

AXONYX INC.

Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional Paid-in Capital	Unearned Compensation Stock Options	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Number of Shares	Amount					
Balance — December 31, 2001 ..	17,247,371	\$17,000	\$ 27,570,000	\$ (30,000)	\$(19,366,000)		\$ 8,191,000
Issuance of common stock and warrants — net of expenses ..	6,486,242	7,000	4,470,000				4,477,000
Amortization				22,000			22,000
Issuance of common stock options and warrants for consulting services			215,000				215,000
Net Loss					(6,256,000)		(6,256,000)
Balance — December 31, 2002 ..	<u>23,733,613</u>	<u>24,000</u>	<u>32,255,000</u>	<u>(8,000)</u>	<u>(25,622,000)</u>		<u>6,649,000</u>
Issuance of common stock and warrants — net of expenses ..	7,706,636	8,000	24,005,000				24,013,000
Amortization				8,000			8,000
Issuance of common stock options and warrants for consulting services			570,000				570,000
Issuance of common stock for consulting services	115,000		205,000				205,000
Exercise of common stock options and warrants	2,364,699	2,000	3,310,000				3,312,000
Net loss					(8,106,000)		(8,106,000)
Balance — December 31, 2003 ..	<u>33,919,948</u>	<u>34,000</u>	<u>60,345,000</u>	<u>—</u>	<u>(33,728,000)</u>		<u>26,651,000</u>
Issuance of common stock and warrants — net of expenses ..	12,727,106	13,000	64,731,000				64,744,000
Issuance of common stock for the acquisition of 52% of Oxis International Inc.	1,618,061	2,000	8,192,000				8,194,000
Issuance of common stock options and warrants for consulting services			2,264,000				2,264,000
Issuance of common stock options			387,000	(387,000)			
Exercise of common stock options and warrants	5,380,403	5,000	13,231,000				13,236,000
Amortization				243,000			243,000
Foreign currency translation adjustment						(14,000)	(14,000)
Net loss					(28,780,000)		(28,780,000)
Balance — December 31, 2004 ..	<u>53,645,518</u>	<u>\$54,000</u>	<u>\$149,150,000</u>	<u>\$(144,000)</u>	<u>\$(62,508,000)</u>	<u>\$(14,000)</u>	<u>\$ 86,538,000</u>

See notes to consolidated financial statements

AXONYX INC.

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2004	2003	2002
Cash flows from operating activities:			
Net loss	\$(28,780,000)	\$(8,106,000)	\$(6,256,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	889,000	16,000	15,000
Amortization of deferred financing costs	772,000		
Minority interest in net loss of subsidiary	(685,000)		
Compensation related to common stock issued for services ..	49,000		
Compensation related to options and warrants issued for services	2,551,000	783,000	237,000
Gain on issuance of subsidiary stock	(1,154,000)		
Changes in:			
Accounts receivable	38,000		
Inventory	49,000		
Other current assets	75,000		
Security deposits and other assets	24,000	47,000	(14,000)
Accounts payable	4,531,000	560,000	120,000
Accrued expenses	1,250,000	(135,000)	(98,000)
Accrued stock-based compensation	(61,000)	404,000	(98,000)
Net cash used in operating activities	(20,452,000)	(6,431,000)	(6,094,000)
Cash flows from investing activities:			
Cash acquired in connection with Oxis acquisition	714,000		
Costs related to Oxis acquisition	(52,000)		
Additions to patents	(297,000)		
Purchase of equipment	(89,000)	(3,000)	
Net cash provided from (used in) investing activities ..	276,000	(3,000)	
Cash flows from financing activities:			
Net proceeds from issuance of common stock and warrants	68,614,000	24,013,000	
Net proceeds from exercise of common stock options and warrants	13,236,000	3,312,000	
Net proceeds from exercise of common stock options in Oxis ...	137,000		
Collection of stock subscriptions receivable and cash held in escrow		4,868,000	
Net cash provided by financing activities	81,987,000	32,193,000	
Net increase (decrease) in cash and cash equivalents	61,811,000	25,759,000	(6,094,000)
Cash and cash equivalents at beginning of period	28,780,000	3,021,000	9,115,000
Cash and cash equivalents at end of period	\$ 90,591,000	\$28,780,000	\$ 3,021,000
Supplemental cash flow disclosures			
Interest paid	\$ 28,000		
Supplemental disclosures of non-cash financing activity:			
Common stock issued in connection with acquisition	\$ 8,194,000		
Unearned compensation recorded for common stock options issued	\$ 387,000		
Bridge loan and accrued interest conversion to common stock — Oxis	\$ 609,000		
Stock subscriptions receivable — Oxis	\$ 2,250,000		
Common stock and warrants issued for stock subscriptions receivable			\$ 3,415,000
Proceeds from the sale of common stock and warrants held in escrow			\$ 1,453,000
Expenses accrued in connection with sale of common stock and warrants			\$ 391,000

See notes to consolidated financial statements

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NOTE A — THE COMPANY

Axonyx Inc. (the "Company") is a biopharmaceutical company, specializing in central nervous system (CNS) neurodegenerative diseases, engaged in the business of acquiring the patent rights to what the Company views as clinical-stage compounds, compounds with strong proof of concept data and compounds ready for proof of concept validation with convincing scientific rationale. The Company's business plan is to further develop and add value to these compounds and then seek to out-license or partner them when it believes it business prudent. The Company has acquired worldwide exclusive patent rights to three main classes of therapeutic compounds designed for the treatment of Alzheimer's disease (AD) and other memory impairments generally associated with elderly and related diseases. There can be no assurance that the Company will be able to license its technology, develop a commercial product, or that the Food and Drug Administration will grant approval to the Company's products. The Company outsources principally all of its research and development activities, which are overseen by Company personnel and scientific consultants.

The Company has progressed the development of Phenserine to late stage clinical trials. As of December 31, 2004, the Company had expected future contractual payments to various clinical research organizations in connection with these trials aggregating \$15,801,000, including \$15,292,000 for 2005. The nature of the clinical research contracts is such that work can be stopped at short notice and the obligation would be to pay costs incurred to date. The results of the 1st Phase III trial were announced on February 7, 2005 and the interim results from the Phase IIb trial were announced on March 11, 2005. See Note J — subsequent events for more details. Overall the results from each trial did not show statistically significant improvements over placebo for the protocol's primary endpoints following 26 weeks of treatment. The Company has decided to halt additional patient recruitment for the ongoing phase III clinical trials in order to evaluate the planned Phenserine clinical development program following recommendations from its Scientific Advisory Board and Safety Steering Committee, as well as the Company's desire to examine opportunities that could optimize further Phenserine development. As a matter of course, the Company continually evaluates its overall drug development and business plan.

As of December 31, 2004, the Company has a 34% ownership interest in OXIS International Inc., ("OXIS"). OXIS develops, manufactures and markets selected therapeutic and diagnostic products. OXIS's research and development efforts are concentrated principally in the development of products to diagnose, treat and prevent diseases associated with free radicals and reactive oxygen species.

NOTE B — SIGNIFICANT ACCOUNTING POLICIES

[1] Principles of consolidation:

The consolidated financial statements include the accounts of Axonyx Europe, B.V., a wholly owned subsidiary organized in Holland. The financial statements also include the accounts of OXIS International Inc. (OXIS) from the acquisition date of January 15, 2004 when the company acquired approximately 52% of the common voting stock of OXIS. The Company's ownership in OXIS was reduced to 34% on December 31, 2004 as the result of a third party financing by OXIS. Although the Company has less than a majority ownership at December 31, 2004, the accounts of OXIS are consolidated as the Company controls the board of directors through a majority of the OXIS board seats. All intercompany balances and transactions have been eliminated in consolidation.

The outside interest on the balance sheet as of December 31, 2004 includes the approximately 66% of OXIS that is not owned by the Company (\$3,905,000). The outside interest also includes a portion of the carrying value of technology for developed patents, net (\$2,040,000) attributable to the reduction in the Company's ownership in OXIS from approximately 52% to approximately 34% as of December 31, 2004.

On February 28, 2005 OXIS announced that Mr. Steven T. Guillen had joined OXIS as President and Chief Executive Officer and as a member of the OXIS Board of Directors. Consequently the Company no longer has a majority of the seats on the OXIS Board, and because the Company's ownership interest now represents

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34% of the OXIS shares outstanding, beginning March 1, 2005 OXIS will no longer be consolidated but rather accounted for using the equity method.

[2] Cash equivalents:

The Company considers all highly liquid short-term investments with original maturities of three months or less at the time of purchase to be cash equivalents. \$4,687,000 in cash is held in OXIS and restricted for use by OXIS.

[3] 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 history of past write-offs and collections and current conditions.

[4] 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:

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

[5] 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 year. 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 \$38,000 and \$16,000 respectively.

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

	<u>2004</u>	<u>2003</u>
Furniture and office equipment	\$207,000	\$ 78,000
Laboratory and manufacturing equipment	3,000	3,000
Property, plant and equipment, at cost	\$210,000	81,000
Accumulated depreciation and amortization	<u>(94,000)</u>	<u>(57,000)</u>
Property, plant and equipment, net	<u>\$116,000</u>	<u>\$ 24,000</u>

[6] Research and development:

Research and development costs are expensed as incurred.

[7] Use of estimates:

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

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Assumptions underlying the carrying amounts of long lived assets represent sensitive estimates subject to change.

[8] Fair value of financial instruments:

The carrying amount reported in the balance sheet for cash and cash equivalents, accounts receivable, stock subscriptions receivable, inventories, accounts payable, and accrued expenses approximates fair value due to the short-term nature of the accounts.

[9] Revenue recognition:

The Company received a milestone payment of \$1,000,000 under the terms of a license agreement in 2003. The Company did not recognize any revenue during the year ended December 31, 2002. Pursuant to the license agreement, the Company may receive milestone payments and royalties from sales of approved drug compounds derived from the licensed technology.

The Company defers recognition of revenue from fees received in advance unless they represent the culmination of a separate earnings process. Such deferred fees are recognized as revenue over the term of the arrangement as they are earned, in accordance with the agreement. License fees represent the culmination of a separate earnings process if they are sold separately without obligating the Company to perform research and development activities or other services. Right to license fees are recognized over the term of the agreement. Nonrefundable, noncreditable license fees that represent the culmination of a separate earnings process are recognized upon execution of the license agreement. Revenue from the achievement of milestone events stipulated in the agreements will be recognized when the milestone is achieved. Royalties will be recognized as revenue when the amounts earned become fixed and determinable.

OXIS manufactures, or has manufactured on a contract basis, products that are sold to customers. OXIS recognizes product sales upon shipment of the product to the customers.

OXIS recognizes license fee revenue for licenses to intellectual property when earned under the terms of the agreements. Generally, revenue is recognized upon transfer of the license unless OXIS has continuing obligations for which fair value cannot be established, in which case the revenue is recognized over the period of the obligation. If there are extended payment terms, OXIS recognized license fee revenue as these payments become due. All arrangements with payments terms beyond 12 months are not considered 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. OXIS recognizes royalty revenue based on reported sales by third party licensees of products containing its materials, software and intellectual property. If there are extended payment terms, royalty revenues are recognized as these payments become due. Non-refundable royalties, for which there are no further performance obligations, are recognized when due under the terms of the agreements.

[10] Stock-based compensation:

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

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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	2002
Reported net loss attributable to common stockholders	\$(28,780,000)	\$ (8,106,000)	\$ (6,256,000)
Stock-based employee compensation included in net loss	243,000		
Stock-based employee compensation determined under the fair value based method	<u>(2,000,000)</u>	<u>(2,515,000)</u>	<u>(3,759,000)</u>
Pro forma net loss	<u>\$(30,537,000)</u>	<u>\$(10,621,000)</u>	<u>\$(10,015,000)</u>
Loss per common share (basic and diluted):			
As reported	\$ (.58)	\$ (.30)	\$ (.36)
Pro forma	(.61)	(.39)	(.58)

In accordance with SFAS No.123, the pro forma amounts do not reflect any other adjustments. Accordingly, the minority interest and effect on the gain on the sale of stock by OXIS pursuant to SEC Staff Accounting Bulletin ("SAB") No.51 are not reflected.

The fair value of each option grant on the date of grant is estimated using the Black-Scholes option-pricing model reflecting the following:

	Year Ended December 31,		
	2004	2003	2002
Risk-free interest rate	2.79%–3.60%	2.27%–3.27%	2.95%–4.8%
Expected dividend yield	0%	0%	0%
Expected life	5–10 years	5–10 years	5–10 years
Expected volatility90–.95	.88–.95	.76–.88
Weighted average grant-date fair value of options granted during the period (including non-employees)	\$4.64	\$1.82	\$1.92

[11] Net loss per common share:

Statement of Financial Accounting Standards No. 128, "Earnings Per Share" ("SFAS 128") requires the reporting of basic and diluted earnings or loss per share. Basic loss per share is calculated by dividing net loss by the weighted average number of outstanding common shares during the year. As all potential common shares are anti-dilutive, their effects are not included in the calculation of diluted loss per share. For the years ended December 31, 2004, 2003, and 2002, potential common shares aggregating 12,364,000, 13,540,000 and 8,813,000, respectively, were excluded in computing the per share amounts.

[12] Concentration of credit risk:

Financial instruments which potentially subject the Company to concentration of credit risks consist principally of cash and cash equivalents. The Company primarily holds its cash and cash equivalents in two money market brokerage accounts and commercial paper. In addition, as of December 31, 2004 and 2003, the Company maintained approximately \$515,000 and \$263,000 respectively, in foreign bank accounts.

The Company enters into research consulting agreements and certain other arrangements which are to be paid in Euro. The Company purchases Euro to meet these obligations on an as needed basis throughout the year.

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[13] Impairment of Long-Lived Assets:

The Company follows statement of Financial Accounting Standard No 144 "Accounting for the Impairment of Long-Lived Assets". Long-lived asset are reviewed for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. Subsequent impairment assessments could result in future impairment charges. Any impairment charge results in the reduction in the carrying value of long-lived assets and reduces our operating results in the period in which the charge arose. As of December 2004 the company determined that no impairment change was needed.

[14] Stock Subscriptions Receivable:

At OXIS, a total of 12,264,158 shares were subscribed for 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, OXIS 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.

[15] Technology for developed products and patents and patents pending:

Technology for developed products acquired in business combinations is amortized over their estimated useful lives of seven to ten years. Accumulated amortization of technology for developed products was \$772,000 and \$0 as of December 31, 2004 and 2003, respectively. Patents are being amortized on a straight-line basis over the shorter of the remaining life of the patent or ten years. A total of \$865,000 of patents pending approval is not currently being amortized. Accumulated amortization as of December 31, 2004 is \$35,000. 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.

[16] Accounting for stock sales by subsidiary:

The Company accounts for stock sales by a subsidiary (Oxis) in accordance with SAB No. 51. Sales of unissued shares by Oxis result in a change in the carrying value of the subsidiary in the Company's consolidated financials. These gains amounted to \$1,154,000 relating to OXIS in 2004, arising primarily from its December private placement financing, the conversion of bridge loans into common stock and from the exercise of employee stock options throughout the year.

NOTE C — DEVELOPMENT AND LICENSING AGREEMENTS

[1] Agreement with New York University ("NYU"):

In April 1997, the Company entered into a research and license agreement with NYU, as subsequently amended, to provide funding and to sponsor research relating to the diagnosis and treatment of Alzheimer's Disease and other amyloidosis disorders, in exchange for a payment by Axonyx of \$25,000 upon signing of the agreement, sixteen consecutive quarterly payments of \$75,000 beginning on April 1, 1997, and 600,000 shares of common stock with a fair value at time of issuance of \$240,000 (issued to NYU and its scientists, collectively "NYU stockholders"). The agreement also provides for payments to NYU aggregating to \$525,000, with an aggregate of \$175,000 payable upon achieving two clinical and regulatory milestones for each of the three types of licensed products. In addition, the Company has agreed to pay NYU royalties of up to 4% of the first \$100 million net sales related to products covered and 2% there after under the agreement with minimum annual royalty payments of \$150,000 beginning in 2004 through the expiration or termination of the agreement in 2015. In 2004, the Company paid NYU its minimum royalty payment of \$150,000 for 2004 and reimbursed NYU for \$9,000 relating to patent costs. During 2003, the Company reimbursed NYU

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for \$36,000 relating to patent costs. Through December 31, 2004, the Company has paid \$1,420,000 to NYU under the agreement.

In addition, in connection with the agreement entered into with NYU and its scientists, the Company granted additional shares of the Company's common stock pursuant to certain anti-dilution provisions at a purchase price of \$.001 per share. The agreements provided for the purchase of additional shares based on a formula of the Company's capital raising activities. During 1999, the Company recorded a charge of approximately \$1,965,000 representing the 305,074 shares deemed issuable (which were issued in 2000) for nominal consideration under the agreement. In 2000, the Company issued an additional 12,295 shares to NYU as final consideration under the anti-dilution provisions and recorded a charge of \$138,000.

Pursuant to the agreement, as amended, the Company or its sub-licensees must achieve certain development milestones, including approval to market in the United States and Europe by December 2009. If these milestones are not achieved, the rights may revert back to NYU. The October 2002 amendment contained releases and waivers of default by NYU and the Company. The technology covered by the NYU Agreement has been sublicensed to Serono (see Note C-3).

[2] Agreement with Cure, L.L.C. ("CURE"):

In February, 1997, the Company entered into a sub-license agreement ("CURE Agreement") with CURE pursuant to which the Company received the rights covering the patents that CURE obtained through the "PHS Patent License Agreement-Exclusive" it entered into with the Public Health Service. Such licensed rights cover the Company's acetylcholinesterase inhibitor, Phenserine and its analogs, and certain butyrylcholinesterase inhibitor compounds. The CURE Agreement provided for a payment by the Company of \$15,000 upon signing of the agreement and a payment of \$10,000 six months after the signing of the agreement. The CURE Agreement also provides for payments to CURE aggregating \$600,000 when certain clinical and regulatory milestones are achieved. In addition, the Company has agreed to pay CURE royalties, of up to 3% of the first \$100 million and 1% thereafter, of net product sales and sub-license royalties, as defined under the agreement, with minimum annual royalty payments of \$10,000 beginning on January 31, 2000, increasing to \$25,000 per annum on commencement of sales of the product until the expiration or termination of the agreement. Any royalty payments made to CURE shall be credited against the minimum payments. Through December 31, 2004, the Company has paid \$100,000 under the CURE Agreement. The agreement, as amended, sets certain deadlines by which the Company must achieve development milestones. If these milestones are not achieved, the rights may revert back to CURE.

[3] Agreement with Applied Research Systems ARS Holding N.V.:

Effective as of May 17, 1999, Axonyx Inc. entered into a Development Agreement and Right to License (the "Development Agreement") with Applied Research Systems ARS Holding N.V., a wholly owned subsidiary of Serono International, SA ("Serono"). Under the Development Agreement, the Company granted to Serono an exclusive right to license its patent rights and know-how regarding its amyloid inhibitory peptide (AIP) and prion inhibitory peptide (PIP) technology.

In 2000, the Company and Serono finalized a definitive Licensing Agreement, pursuant to which the exclusive worldwide patent rights to the Axonyx's AIP and PIP technology were granted to Serono. The Company received a nonrefundable, noncreditable license fee of \$1.5 million, which was recognized as revenue since the Company is not responsible for any ongoing research and development activities or any other services with respect to this arrangement and it represented the culmination of a separate earnings process.

In April 2003, Axonyx received a milestone payment of \$1,000,000 from Serono under the terms of the License Agreement, which was triggered when Serono initiated a Phase I clinical trial with a patented product.

Pursuant to the Licensing Agreement, the Company may receive milestone payments in the future.

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The Company learned in 2004 that Serono was evaluating whether to continue further development of the licensed technologies and discussions were initiated with Serono to investigate whether a collaborative agreement could be negotiated. Any final decision to delay or terminate development on the part of Serono would mean that our receipt of any further payments under the License Agreement would be either delayed or eliminated. During 2004, the Company and Serono discussed the existing licensing agreements and possible alternative structures and collaborations that might be used to potentially exploit the licensed technology. As a result of these discussions, in July 2004, we signed a non-binding Memorandum of Understanding (MOU) for the research and joint development of therapeutic compounds including the Amyloid Inhibitory and Prion Inhibitory Peptides, and diagnostic technologies in the field of protein misfolding disorders such as Parkinson's Disease, Down's Syndrome, Diabetic disorders, Lou Gehrig's Disease, Alzheimer's Disease, Transmissible Spongiform Encephalopathies (TSE's) i.e. Mad Cow Disease (BSE) and Creutzfeldt Jakob Disease new variant (CJDnv).

Since the signing of the MOU, the parties have been negotiating the terms of definitive agreements. If the agreements contemplated under the MOU are finalized, the milestone payments under the original licensing agreements to SERONO will not occur.

Regardless of whether definitive agreements are completed or whether future milestone payments are received, the Company is obligated to pay to NYU its minimum annual royalty of \$150,000.

[4] Agreement with David Small/Monash University:

Effective September 1, 2002, we entered into a Research Agreement and a Consulting Agreement with David Henry Small, Ph.D., and an Intellectual Property Assignment Agreement with David Henry Small, Ph.D., Marie-Isabel Aquilar, Ph.D., and Supundi Subasinghe ("Assignment Agreement"). Each of these agreements relate to the development of an assay method for the rapid screening of potential drug candidates for the treatment of Alzheimer's Disease. The Research Agreement funds a research project concerning further development of the assay method under the guidance of Dr. Small for a three year period commencing October 1, 2002, for Australian \$90,000 per year. The research project pursuant to the Research Agreement is being undertaken by Dr. Small at Monash University in Clayton, Australia.

[5] Agreement with NOTOX:

During 2002, the Company awarded a contract of approximately \$1.25 million to NOTOX Safety and Environmental Research B.V. for research and development activities relating to Phenserine. Research and development expenses for the years ended December 31, 2004, 2003 and 2002 include \$260,000, \$406,000 and \$493,000 respectively, relating to this contract.

[6] Research and Development Contracts:

For the year ended December 31, 2004 the Company incurred significant research and development expenses primarily attributable to the start of additional Phenserine clinical trials. The Company has a variety of contracts with various clinical research organizations. The nature of these contracts is such that work may have to be stopped with very short notice and then the Company will only be obligated to pay costs incurred to date. The remaining payments for these research and development contracts amounts to \$15,801,000 with \$15,292,000 falling into 2005 and the balance in 2006.

[7] Other:

The Company entered into agreements with three individuals relating to the development of an assay method for the rapid screening of potential drug candidates for the treatment of Alzheimer's disease. Pursuant to these agreements, the Company is obligated for a three-year period commencing October 1, 2002 to fund Australian \$90,000 (approximately \$49,000 in US dollars) per year. Under the agreements, all of the rights, title and

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interest relating to a patent application concerning the assay method was assigned in return for revenue sharing upon commercialization of the assay method. The Company also agreed to pay certain legal fees on behalf of the assignors, which are creditable against future royalties payable under the revenue sharing provisions. The Company entered into a consulting agreement with one of the three individuals for a three-year period, commencing September 1, 2002 for Australian \$20,000 (approximately \$11,000 in US dollars) per year.

NOTE D — INCOME TAXES

At December 31, 2004, the Company has available a Federal net operating loss carryforward of approximately \$18,614,000, expiring through 2024, that may be used to offset future federal taxable income. At December 31, 2004, the Company also has a research and development credit carryforward of approximately \$1,278,000 available to offset future federal income tax. The use of net operating loss and research and development credit carryforwards and built-in losses relating to expenses not yet deducted for tax purposes are subject to limitation due to a change in the Company's ownership as defined by Sections 382 and 383 of the Internal Revenue Code.

At December 31, 2004 there are \$39,359,000 of timing differences in reporting items for tax and financial accounting purposes, relating to research and development expenses and stock option charges. At December 31, 2004, and 2003, the Company has deferred tax assets of approximately \$27,818,000 and \$14,261,000, respectively. The deferred tax asset at December 31, 2004 is comprised of the tax effect of the net operating loss carryforwards (\$8,522,000), the timing differences (\$15,841,000 for capitalized research and development expenses and \$2,177,000 for stock-based compensation) and the research and development credit carryforwards (\$1,278,000). The deferred tax asset at December 31, 2003 is comprised of the tax effect of the net operating loss carryforwards (\$5,497,000) the timing differences (\$7,169,000 for capitalized research and development expenses and \$941,000 for stock-based compensation) and the research and development credit carryforwards (\$654,000). The Company has not recorded a benefit from its deferred tax asset because realization of the benefit is uncertain. Accordingly, a valuation allowance, which increased by approximately \$13,557,000, \$3,778,000 and \$2,755,000 during 2004, 2003 and 2002, respectively, has been provided for the full amount of the deferred tax asset.

NOTE E — RELATED PARTY TRANSACTIONS

In 2002, the Company received data management and reporting services from Clinfo Systems, LLC ("Clinfo") in connection with certain clinical trials being conducted. A former officer of the Company is a founding member and fifty percent owner of Clinfo. The Company incurred \$57,000 of expenses in 2002 from services provided by Clinfo.

NOTE F — STOCKHOLDERS' EQUITY

[1] Sale of common stock and warrants:

In December 2002, the Company sold 6,486,000 shares of common stock with 3,243,000 warrants yielding net proceeds of \$4,477,000 after deducting offering costs of \$391,000. The gross proceeds of \$4,868,000 was collected in 2003. The warrants are exercisable through December 2007 at \$0.69 per share. In addition, the Company issued 200,000 warrants on January 15, 2003 to a consultant to the Company related to the transaction. The 200,000 warrants are exercisable through January 15, 2008 at \$1.00 per share. At December 31, 2002 the Company had \$1,453,000 in an escrow account and \$3,415,000 of stock subscription receivable, which were received in January 2003.

In June 2003, the Company received proceeds of \$575,000 in connection with a private placement of 230,000 shares of common stock.

In September 2003, the Company received net proceeds of \$23,438,000 from a private placement of 7,477,000 shares of common stock and 5,607,000 warrants. The warrants are exercisable through September 2008 at \$3.50 per share.

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During 2003, the Company received proceeds of \$3,311,000 from the exercise of warrants into 2,314,000 shares of common stock.

In January 2004, the Company completed a private placement for \$50 million of securities through the sale of 9,650,183 shares of common stock. This placement also involved the issuance to the investor group of five-year warrants to purchase an additional 2,412,546 shares of the Company's stock at an exercise price of \$7.25 per share. Each share of stock and one-quarter warrant was sold for \$5.18.

Also in January 2004, the Company issued 1,618,061 shares of common stock valued at \$8,194,000 in conjunction with the Company's acquisition of 52% of the outstanding voting stock of Oxis International, Inc.

In May 2004, the Company completed a private placement for \$20 million of securities through the sale of 3,076,923 shares of common stock at \$6.50 per share with new institutional investors. This placement also involved the issuance to the investor group of five-year warrants to purchase an additional 923,077 shares of the Company's stock at an exercise price of \$8.50 per share.

In 2004, the Company received proceeds of \$13,236,000 from the exercise of options and warrants into 5,380,403 shares of common stock.

[2] Warrants:

At December 31, 2004, outstanding warrants to acquire shares of the Company's common stock are as follows:

<u>Number of Shares</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
954,000	\$8.50	May 6, 2009
413,000	5.00	June 3, 2005
2,529,000	3.50	September 11, 2008
2,968,000	7.25	January 8, 2009
24,000	6.81	February 13, 2006
466,000	.69	December 31, 2007
33,000	5.00	December 19, 2008
<u>200,000</u>	1.00	January 15, 2008
<u>7,587,000</u>		

The weighted average exercise price of warrants outstanding at December 31, 2004 was \$5.46 and the weighted average remaining contractual life of the warrants was 3.66 years.

[3] Stock options:

During 1998, the Board of Directors and the stockholders of the Company approved a Stock Option Plan ("1998 Plan"), which provides for the granting of options to purchase up to 2,000,000 shares of common stock, pursuant to which officers, directors, advisors and consultants are eligible to receive incentive and/or nonstatutory stock options. Incentive stock options granted under the 1998 Plan are exercisable for a period of up to 10 years from date of grant at an exercise price which is not less than the fair value on date of grant, except that the exercise period of options granted to a stockholder owning more than 10% of the outstanding capital stock may not exceed five years and their exercise price may not be less than 110% of the fair value of the common stock at date of grant. Vesting of 1998 Plan options varies from fully vested at the date of grant to multiple year apportionment of vesting as determined by the Board of Directors.

In 2000, the Board of Directors and the stockholders of the Company approved a Stock Option Plan ("2000 Plan") which provides for the granting of options to purchase up to 1,000,000 shares of common stock and pursuant to which officers, directors, advisors and consultants are eligible to receive incentive and/or nonstatutory stock options. Incentive stock options granted under the 2000 Plan are exercisable for a period

AXONYX INC.
Notes to Consolidated Financial Statements
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of up to 10 years from date of grant at an exercise price which is not less than the fair value on date of grant, except that the exercise period of options granted to a stockholder owning more than 10% of the outstanding capital stock may not exceed five years and their exercise price may not be less than 110% of the fair value of the common stock at date of grant. Vesting of 2000 Plan options varies from fully vested at the date of grant to multiple year apportionment of vesting as determined by the Board of Directors.

On December 11, 2001, the Company amended the 2000 Plan to increase the aggregate number of shares from 1,000,000 to 2,000,000. Stockholder approval for the increase was received in June 2002. During 2001, the Company granted 515,000 options, with an exercise price of \$3.16, that were granted subject to such stockholder approval, which was given in 2002. Accordingly, these options were accounted for as if they were granted during the year ended December 31, 2002.

Pursuant to the 2000 stock option plan as amended, 750,000 options were added to the share reserve effective January 1, 2003 and January 1, 2004.

On March 30, 2004, the Company amended the 2000 Plan to increase the aggregate number of shares from 3,500,000 to 7,500,000. Stockholder approval for the increase was received in June 2004.

For the years ended December 31, 2004, 2003 and 2002, the Company granted 497,000, 300,000 and 67,500 options, respectively, to consultants and recorded expenses of \$2,264,000, \$570,000 and \$215,000, respectively, relating to the vested portion of these options. Accrued expenses at December 31, 2004, 2003, and 2002 include an additional \$399,000, \$460,000 and \$56,000, respectively, for the estimated fair value of unvested options issued to consultants.

Stock option activity under the 1998 Plan is summarized as follows:

	Year Ended December 31,					
	2004		2003		2002	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options at beginning of year	1,375,000	\$5.72	1,790,000	\$6.37	1,971,000	\$6.66
Options issued			50,000	1.11	8,000	1.35
Options exercised	(50,000)	.02	(50,000)	.02		
Options forfeited	(341,000)	5.83	(415,000)	8.68	(189,000)	9.14
Options at end of year	<u>984,000</u>	<u>5.96</u>	<u>1,375,000</u>	5.72	<u>1,790,000</u>	6.37
Options exercisable at end of year ...	<u>949,000</u>	<u>6.53</u>	<u>1,313,000</u>	5.77	<u>1,528,000</u>	5.94

The 1998 Plan terminated January 15, 2003.

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Stock option activity under the 2000 Plan is summarized as follows:

	Year Ended December 31,					
	2004		2003		2002	
	Shares	Weighted Average Price	Shares	Weighted Average Price	Shares	Weighted Average Price
Options at beginning of year	2,738,000	\$2.86	1,671,000	\$3.45	924,000	\$4.22
Options issued	1,566,000	5.39	1,107,000	2.08	847,000	2.57
Options exercised	(633,000)	1.91				
Options forfeited	(221,000)	2.54	(40,000)	5.54	(100,000)	3.16
Options at end of year	<u>3,450,000</u>	4.21	<u>2,738,000</u>	2.86	<u>1,671,000</u>	3.45
Options exercisable at end of year ...	<u>2,073,000</u>	3.85	<u>1,537,000</u>	3.25	<u>710,000</u>	4.14

As of December 31, 2004, 3,392,000 options are available for future grant under the 2000 plan. In 2003, the Company had agreed to grant 319,000 options, with exercise prices ranging from \$3.61 to \$3.76, effective January 1, 2004. These awards resulted in an aggregate compensation cost of \$387,000, which is being recognized over the related vesting periods.

Stock option activity outside the Plans is summarized as follows:

	Year Ended December 31,					
	2004		2003		2002	
	Shares	Weighted Average Price	Shares	Weighted Average Price	Shares	Weighted Average Price
Options at beginning of year	375,000	\$4.41	129,000	\$7.81	129,000	\$7.81
Options issued			275,000	3.06		
Options exercised	(32,000)	3.41				
Options forfeited			(29,000)	6.72		
Options at end of year	<u>343,000</u>	4.51	<u>375,000</u>	4.41	<u>129,000</u>	7.81
Options exercisable at end of year ...	<u>305,000</u>	4.74	<u>207,000</u>	5.63	<u>124,000</u>	8.17

Additional information with respect to option activity is summarized as follows:

Range of Exercise Prices	As of December 31, 2004					
	Options Outstanding			Options Exercisable		
	Shares	Weighted Average Remaining Contractually (in years)	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	
\$.02-\$.84	162,000	6.06	\$.58	122,000	\$.50	
\$1.00-\$1.35	285,000	6.21	1.11	50,000	1.07	
\$2.07-\$3.16	1,446,000	5.45	2.94	1,248,000	2.93	
\$3.61-\$6.68	1,762,000	6.07	4.58	1,085,000	4.51	
\$7.00-\$9.00	849,000	6.90	7.54	549,000	7.81	
\$9.50-\$11.50	273,000	5.11	10.33	273,000	10.33	
	<u>4,777,000</u>	5.98	4.60	<u>3,327,000</u>	4.74	

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NOTE G — COMMITMENTS AND OTHER MATTERS

The Company occupied office space under a sublease which expired in February 2003. Upon expiration of the lease, the Company's corporate offices were relocated and a short-term renewable lease was executed. There are no minimum future annual rental payments. OXIS office, laboratory and manufacturing space is leased under an agreement expiring in November 2005.

Rent expense was approximately \$294,000, \$112,000 and \$268,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

See Note C with respect to the Company's obligations pursuant to various research and development agreements.

NOTE H — Quarterly Results (Unaudited)

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
2004:				
Revenue.....	\$ 478,000	\$ 433,000	\$ 954,000	\$ 410,000
Net loss.....	(5,991,000)	(7,132,000)	(6,693,000)	(8,964,000)
Loss per share — basic and diluted (a)	(0.13)	(0.14)	(0.13)	(0.17)
2003:				
Revenue.....		\$ 1,000,000		
Net loss.....	\$(1,575,000)	(1,247,000)	\$(1,803,000)	\$(3,481,000)
Loss per share — basic and diluted (a)	(0.07)	(0.05)	(0.07)	(0.10)

(a) Per common share amounts for the quarters and full year have been calculated separately. Accordingly, quarterly amounts do not necessarily add to the annual amount because of differences in the weighted average common shares outstanding during each period due to the effect of the Company's issuing shares of its common stock during the year.

NOTE I — Acquisition of OXIS International Inc.

On January 15, 2004, the Company entered into agreements to acquire approximately 52% of the outstanding voting stock of OXIS. OXIS is a biopharmaceutical company engaged in the development of research diagnostics, nutraceuticals and therapeutics in the field of oxidative stress. Under the terms of separate agreements entered into with several holders of OXIS common stock, the Company acquired an aggregate of approximately 14 million shares of OXIS stock, in consideration for the issuance of an aggregate of approximately 1.6 million shares of our unregistered common stock, which the Company registered in May 2004. The Company's Chairman and then-Chief Executive Officer owned 1,161,532 shares of OXIS common stock, representing approximately 4% of the OXIS's voting stock. Those shares of OXIS's common stock were not acquired.

The aggregate purchase price was \$8,246,000, which includes the market value of the Company's common shares that were issued as consideration and transaction costs.

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The allocation of the cost of the acquisition is as follows:

Current assets	\$ 1,492,000
Equipment	41,000
Technology and developed products (3)	7,622,000
Patents and other assets	765,000
Current liabilities	(1,039,000)
Minority interest	(635,000)
Deferred tax liability (1)	(3,011,000)
Deferred tax liability (2)	<u>3,011,000</u>
	<u>\$ 8,246,000</u>

- (1) Represents the tax effect of the excess of the financial statement basis over the tax basis for acquired technology for developed products.
- (2) Represents the tax benefit of OXIS net operating loss carryforward and deductible temporary differences recognized as an offset against the deferred tax liability attributable to the acquired technology for developed products.
- (3) Includes the excess of the purchase price over the Company's portion of the net assets of OXIS on the date of acquisition, which amounted to \$7,529,000.

The operating results of OXIS are included in the consolidated results of operations since the date of acquisition. The following pro forma information gives effect to the acquisition as if it had occurred on the first day of each of the years ended December 31, 2004 and 2003.

	<u>2004</u>	<u>2003</u>
Total revenues	\$ 2,364,000	\$ 3,740,000
Net loss including minority interest in subsidiary	(29,550,000)	(9,650,000)
Net loss	(28,865,000)	(9,278,000)
Basic and diluted net loss per common share	(0.58)	(0.32)

During 2004 the Company loaned \$1.2 million to OXIS, which has been eliminated in consolidation as of December 31, 2004. Pursuant to its terms, OXIS repaid the loan with accrued interest in January 2005.

On January 9, 2004, Oxis received \$570,000 in loans and issued promissory notes convertible into common stock at \$0.40 per share (\$0.15 under certain circumstances). Oxis also issued warrants to the lenders exercisable for up to 1,250,000 shares of common stock, plus additional shares for accrued interest, at an exercise price of \$0.50 per share. Oxis recorded \$570,000 of debt discount, which is included in financing fees in the accompanying financial statements for the year ended December 31, 2004. In December 2004, all of the promissory notes and accrued interest were converted into 1,520,932 shares of common stock. In connection with the note holders waiving their right to convert at \$0.15 per share (which had been triggered), Oxis issued 760,467 warrants. Each warrant entitles the holder to purchase one share of Oxis 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. Certain of the lenders sold shares of Oxis common stock to the Company on January 15, 2004.

Operating Segments

The Company is organized into two reportable segments beginning January 15, 2004: Axonyx and OXIS. While OXIS has historically been organized into two reportable segments (health products and therapeutic development), Oxis currently manages its operations in one segment in order to better monitor and manage its basic business: the development of research diagnostics, nutraceutical and therapeutic products.

The following table presents information about the Company's two operating segments:

AXONYX INC.
Notes to Consolidated Financial Statements
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	<u>Axonix Inc.</u>	<u>Oxis Int'l Inc.</u>	<u>Total</u>
<i>Year ended December 31, 2004</i>			
Revenue including minority interest		\$ 2,275,000	\$ 2,275,000
Segment loss	\$(26,172,000)	\$(2,608,000)	\$(28,780,000)
Segment assets including minority interest at December 31, 2004	\$ 85,991,000	\$15,403,000	\$101,394,000

NOTE J — Subsequent Events

- (1) The Company and several of its current officers have been named as defendants in purported shareholder class action lawsuits alleging violations of federal securities laws. One lawsuit was filed on February 15, 2005, and is pending in the U.S. District Court for the Southern District of New York, and another was filed on February 24, 2005 in the same court. These lawsuits assert claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of our common stock during the period from June 26, 2003, through and including February 4, 2005 (the "Class Period"). The complaints allege generally that the defendants knowingly or recklessly made false or misleading statements during the Class Period regarding the effectiveness of Phenserine in treating mild to moderate Alzheimer's disease, which had the effect of artificially inflating the price of our shares. The complaints seek unspecified damages. The Company believes these complaints are without merit and intends to defend these lawsuits vigorously. However, there can be no assurance that the Company will prevail in these actions, and, if the outcomes are unfavorable, the Company's reputation, profitability and share price could be adversely affected.
- (2) On February 7, 2005 the Company announced that the top line outcome of its first Phase III clinical trial with Phenserine, in development for mild to moderate Alzheimer's disease (AD), showed that overall there was not a statistically significant improvement over placebo for the protocol's primary endpoints following 26 weeks of treatment. The Company has halted additional patient recruitment for the ongoing phase III clinical trials in order to evaluate the planned Phenserine clinical development program following recommendations from its Scientific Advisory Board and Safety Steering Committee, as well as the Company's desire to examine opportunities that could optimize further Phenserine development.
- (3) On February 28, 2005 OXIS announced that Mr. Steven T. Guillen had joined OXIS as President and Chief Executive Officer and as a member of the OXIS Board of Directors. Consequently the Company no longer has a majority of the seats on the OXIS Board, and because the Company's ownership interest now represents 34% of the OXIS shares outstanding, beginning March 1, 2005 OXIS will no longer be consolidated but rather accounted for using the equity method.
- (4) On March 3, 2005, the Company announced that Gosse Bruinsma, M.D., has become the Chief Executive Officer of the Company, in addition to continuing to be its President and COO. Dr. Marvin Hausman remains as the Chairman of the Board.
- (5) On March 11, 2005 the Company announced interim statistical results from the first 37 patients in a Phase IIb clinical trial designed to evaluate the effects of Phenserine tartrate on cerebrospinal fluid (CSF) concentrations of beta-Amyloid (Ab 1-42) in Alzheimer's Disease (AD) patients. The Company scheduled this interim analysis to assess the benefit of continuing enrollment to the target of 150 patients, and the data produced was sufficient to suggest a dose response resulting in a lowering of Ab 1-42 in the CSF of Alzheimer's patients. The Company believes that the results obtained from this interim analysis of 37 patients justifies continued enrollment to one of the two dose groups (15mg) in the study. Completion of patient enrollment of this trial is expected in the second quarter of 2005.

AXONYX INC.

**Exhibits filed with Annual Report on Form 10-K
for the fiscal year ended December 31, 2004**

- 14 Code of Business Conduct and Ethics
- 23.1 Consent of Eisner LLP
- 31.1 Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
- 31.2 Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
- 32 Section 1350 Certification of Chief Executive Officer and Chief Financial Officer

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AXONYX INC.
CODE OF BUSINESS CONDUCT AND ETHICS

Introduction

This Code of Business Conduct and Ethics describes the basic principles of conduct that we share as officers and employees of Axonyx Inc. This Code also applies to our directors and should be provided to and followed by our agents and representatives, including consultants. This Code is intended to comply with Nasdaq's Rule 4350(n) and Section 406 of the Sarbanes-Oxley Act of 2002 and the regulations of the Securities and Exchange Commission adopted with respect thereto. Violation of this Code may result in disciplinary action, varying from reprimand to dismissal.

This Code is intended to provide a broad overview of basic ethical principles that guide our conduct. It is our policy to conduct our business affairs honestly and in an ethical manner. In some circumstances, we maintain more specific policies on the topics referred to in this Code. Should you have any questions regarding these policies, please contact S. Colin Neill or his successor as CFO.

Compliance with Laws, Rules and Regulations

We comply with all laws, rules, and regulations of the places where we do business. If a law, rule, or regulation is unclear, or conflicts with a provision of this Code, you should seek advice from our CFO but always seek to act in accordance with the ethical standards described in this Code. You are expected to comply with all local country laws in conducting the Company's business. If you violate these laws or regulations in performing your duties for the Company, you not only risk individual indictment, prosecution and penalties, and civil actions and penalties, you also subject the Company to the same risks and penalties. If you violate these laws in performing your duties for the Company, you may be subject to immediate disciplinary action, including possible termination of your employment or affiliation with the Company.

Conflicts of Interest

We conduct our business affairs in the best interest of our Company and should therefore avoid situations where our private interests interfere in any way with our Company's interests. We need to be especially sensitive to situations that have even the appearance of impropriety and promptly report them to a supervisor, or if appropriate, a more senior manager. If you believe that a transaction, relationship or other circumstance creates or may create a conflict of interest, you should promptly report this concern. It is our policy that circumstances that pose a conflict of interest for our non-director and non-executive officer employees are prohibited unless a waiver is obtained from a senior manager. Any waiver of this conflict of interest policy for a director or executive officer may only be made by our Board or a committee of our Board, and any waiver will be promptly disclosed.

Record-Keeping

We require honest and accurate recording and reporting of information to make responsible business decisions. We document and record our business expenses accurately. Questionable expenses should be discussed with our CFO.

We avoid exaggeration, derogatory remarks, guesswork, or inappropriate characterizations of people and companies in our business records and communications. We maintain our records according to our record retention policies. In accordance with those policies, in the event of litigation or governmental investigation, please consult our CFO.

Senior Officers (the Company's Chief Executive Officer ("CEO"), Chief Operating Officer ("COO"), Chief Financial Officer ("CFO"), principal accounting officer or controller and persons performing similar functions, persons who meet the requirements of Item 406 of Regulation S-K and such other Company officers as are designated from time to time by the Audit Committee of the Board of Directors) are also responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The Senior Officers will take all necessary steps to ensure compliance with established accounting procedures, the Company's system of internal controls and generally accepted

accounting principles. Senior Officers will ensure that the Company makes and keeps books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company. Senior Officers will also ensure that the Company devises and maintains a system of internal accounting controls sufficient to provide reasonable assurances that:

- transactions are executed in accordance with management's general or specific authorization;
- transactions are recorded as necessary (a) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (b) to maintain accountability for assets;
- access to assets is permitted, and receipts and expenditures are made, only in accordance with management's general or specific authorization; and
- the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences, all to permit prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on the Company's financial statements.

Any attempt to enter inaccurate or fraudulent information into the Company's accounting system will not be tolerated and will result in disciplinary action, up to and including termination of employment.

Special Ethics Obligations For Employees With Financial Reporting Responsibilities

Senior Officers each bear a special responsibility for promoting integrity throughout the Company. Furthermore, the Senior Officers have a responsibility to foster a culture throughout the Company as a whole that ensures the fair and timely reporting of the Company's results of operation and financial condition and other financial information.

Because of this special role, the Senior Officers are bound by the following Financial Officer Code of Ethics, and by accepting the Code of Business Conduct and Ethics each agrees that he or she will:

- Perform his or her duties in an honest and ethical manner.
- Handle all actual or apparent conflicts of interest between his or her personal and professional relationships in an ethical manner.
- Take all necessary actions to ensure full, fair, accurate, timely, and understandable disclosure in reports and documents that the Company files with, or submits to, government agencies and in other public communications.
- Comply with all applicable laws, rules and regulations of federal, state and local governments.
- Proactively promote and be an example of ethical behavior in the work environment.

Public Reporting

We are a public company and as a result file reports and other documents with the Securities and Exchange Commission (SEC) and the stock exchanges on which our securities trade. As well, we issue press releases and make other public statements that include financial and other information about our business, financial condition and results of operations. We endeavor to make full, fair, accurate, timely and understandable disclosure in reports and documents we file with, or submit to, the SEC and in our press releases and public communications.

We require cooperation and open communication with our outside auditors. It is illegal to take any action to fraudulently influence, coerce, manipulate, or mislead any external auditor engaged in the performance of an audit of our financial statements.

The laws and regulations applicable to filings made with the SEC, including those applicable to accounting matters, are complex. While the ultimate responsibility for the information included in these reports rests with senior management, numerous other employees participate in the preparation of these reports or provide information included in these reports. We maintain disclosure controls and procedures to ensure that the information included in the reports that we file or submit to the SEC is collected and communicated to senior management in order to permit timely disclosure of the required information.

If you are requested to provide, review or certify information in connection with our disclosure controls and procedures, you must provide the requested information or otherwise respond in a full, accurate and timely manner. Moreover, even in the absence of a specific request, you should report any information that you believe should be considered for disclosure in our reports to the SEC.

If you have questions or are uncertain as to how our disclosure controls and procedures may apply in a specific circumstance, promptly contact your supervisor or a more senior manager. We want you to ask questions and seek advice. Additional information regarding how to report your questions or concerns (including on a confidential, anonymous basis) is included below in this Code.

Insider Trading

We do not trade in Company stock on the basis of material, non-public information concerning the Company, nor do we "tip" others who may trade in Company securities. Please also refer to the Axonyx Inc. Policy Statement on Insider Trading, as amended and restated.

Corporate Opportunities

We do not personally take opportunities that are discovered through the use of Company property, information or position without the prior consent of our Board. Our directors, officers, and employees are also prohibited from competing with the Company.

Competition and Fair Dealing

We outperform our competition fairly and honestly by developing leading products based on design and performance and providing high quality service in a timely and efficient manner. We do not engage in unethical or illegal business practices such as stealing proprietary information, possessing trade secret information that was obtained without the owner's consent, or inducing disclosure of this type of information by past or present employees of other companies.

Business Entertainment and Gifts

We recognize that business entertainment and gifts are meant to create good will and sound working relationships, not to gain unfair advantage with customers or suppliers. Neither we nor our family members offer, give, or accept any gift or entertainment unless it: (a) is not a cash gift, (b) is consistent with customary business practices, (c) is not excessive in value, (d) cannot be construed as a bribe or payoff, and (e) does not violate any laws or regulations. Any questionable gift or invitation should be discussed with a supervisor, or, if appropriate, a more senior manager.

Discrimination and Harassment

The diversity of our employees is a tremendous asset. We provide equal opportunity in all aspects of employment and will not tolerate discrimination or harassment of any kind. Derogatory comments based on racial or ethnic characteristics, unwelcome sexual advances and similar behavior are prohibited.

Health and Safety

We strive to provide a safe and healthy work environment. We ensure a safe and healthy work environment by following safety and health rules and practices and promptly reporting accidents, injuries and unsafe equipment, practices, or conditions to a supervisor or more senior manager.

We do not permit violence or threatening behavior in our workplaces. We report to work in condition to perform our duties at our best, free from the influence of illegal drugs or alcohol. We do not tolerate the use of illegal drugs in the workplace.

Confidentiality

We protect confidential information. Confidential information includes proprietary information such as our trade secrets, patents, trademarks, trade names, copyrights, business, marketing plans, sales forecasts, proprietary software, designs, databases, records, salary information, and unpublished financial data and reports, as well as any non-public information that might be of use to competitors or harmful to us or our customers if disclosed. It also

includes information that suppliers and customers have entrusted to us on a confidential basis. Our personal obligation not to disclose confidential information continues even after employment ends.

Protection and Proper Use of Company Assets

Theft, carelessness, and waste of Company assets have a direct impact on our profitability and should be avoided. Any suspected incident of fraud or theft should be immediately reported to a supervisor or, if appropriate, a more senior manager for investigation. We carefully safeguard our confidential information. Unauthorized use or distribution of confidential information is prohibited and could also be illegal, resulting in civil or even criminal penalties.

Payments to Government Personnel

In compliance with the United States Foreign Corrupt Practices Act we do not give anything of value, directly or indirectly, to officials of foreign governments or foreign political candidates in order to obtain or retain business. We do not promise, offer, or deliver to any foreign or domestic government employee or official any gift, favor, or other gratuity that would be illegal. Our CFO can provide guidance in this area.

The laws or customs of other countries in which we operate may be less clear. It is our policy to comply with those laws or customs; however, if a local law or custom seems to contradict the principles described in this Code, contact our CFO for guidance.

Political Contributions

No employee shall make any political contribution or support in the Company's name.

Waivers

Only our Board may waive a provision of this Code for our executive officers or directors, and any waiver will be promptly disclosed to the public. Waivers of this Code for any other employee may be made only by our COO, and then only under special circumstances.

Reporting Violations of Company Policies and Receipt of Complaints Regarding Financial Reporting or Accounting Issues

You should report any violation or suspected violation of this Code to the appropriate Company personnel or via the Company's anonymous and confidential reporting procedures.

The Company's efforts to ensure observance of, and adherence to, the goals and policies outlined in this Code mandate that you promptly bring to the attention of our CFO, any material transaction, relationship, act, failure to act, occurrence or practice that you believe, in good faith, is inconsistent with, in violation, or reasonably could be expected to give rise to a violation, of this Code. You should report any suspected violations of the Company's financial reporting obligations or any complaints or concerns about questionable accounting or auditing practices in accordance with the procedures set forth below.

Here are some approaches to handling your reporting obligations:

- In the event you believe a violation of the Code, or a violation of applicable laws and/or governmental regulations has occurred or you have observed or become aware of conduct which appears to be contrary to the Code, immediately report the situation to our CFO. Senior Officers who receive any report of a suspected violation must report the matter to the Audit Committee.
- If you have or receive notice of a complaint or concern regarding the Company's financial disclosure, accounting practices, internal accounting controls, auditing, or questionable accounting or auditing matters, you must immediately advise the Chairman of the Audit Committee.

- If you wish to report any such matters anonymously or confidentially, then you may do so as follows:

- Mail a description of the suspected violation or other complaint or concern to:

S. Colin Neill
[or his successor as CFO]
500 Seventh Avenue, 10th Floor
New York, NY 10018
[or the current executive offices of the Company]

- Use common sense and good judgment; Act in good faith. You are expected to become familiar with and to understand the requirements of the Code. If you become aware of a suspected violation, don't try to investigate it or resolve it on your own. Prompt disclosure to the appropriate parties is vital to ensuring a thorough and timely investigation and resolution. The circumstances should be reviewed by appropriate personnel as promptly as possible, and delay may affect the results of any investigation. A violation of the Code, or of applicable laws and/or governmental regulations is a serious matter and could have legal implications. Allegations of such behavior are not taken lightly and should not be made to embarrass someone or put him or her in a false light. Reports of suspected violations should always be made in good faith.
- Internal investigation. When an alleged violation of the Code, applicable laws and/or governmental regulations is reported, the Company will take appropriate action in accordance with the compliance procedures outlined in the Code. You are expected to cooperate in internal investigations of alleged misconduct or violations of the Code or of applicable laws or regulations.
- No fear of retaliation. It is Company policy that there be no intentional retaliation against any person who provides truthful information to a Company or law enforcement official concerning a possible violation of any law, regulation or Company policy, including this Code. Persons who retaliate may be subject to civil, criminal and administrative penalties, as well as disciplinary action, up to and including termination of employment. In cases in which you report a suspected violation in good faith and are not engaged in the questionable conduct, the Company will attempt to keep its discussions with you confidential to the extent reasonably possible. In the course of its investigation, the Company may find it necessary to share information with others on a "need to know" basis. No retaliation shall be taken against you for reporting alleged violations while acting in good faith.

Compliance Procedures

The Company has established this Code as part of its overall policies and procedures. To the extent that other Company policies and procedures conflict with this Code, you should follow this Code. The Code applies to all Company directors and Company employees, including all officers, in all locations.

The Code is based on the Company's core values, good business practices and applicable law. The existence of a Code, however, does not ensure that directors, officers and employees will comply with it or act in a legal and ethical manner. To achieve optimal legal and ethical behavior, the individuals subject to the Code must know and understand the Code as it applies to them and as it applies to others. You must champion the Code and assist others in knowing and understanding it.

- Compliance. You are expected to become familiar with and understand the requirements of the Code. Most importantly, you must comply with it.
- CEO Responsibility. The Company's CEO shall be responsible for ensuring that the Code is established and effectively communicated to all employees, officers and directors. Although the day-to-day compliance issues will be the responsibility of the Company's CFO and COO, the CEO has ultimate accountability with respect to the overall implementation of and successful compliance with the Code.
- Internal Reporting of Violations. The Company's efforts to ensure observance of, and adherence to, the goals and policies outlined in this Code mandate that all employees, officers and directors of the Company report suspected violations in accordance with this Code.
- Screening of Employees. The Company shall exercise due diligence when hiring and promoting employees and, in particular, when conducting an employment search for a position involving the exercise of substantial

discretionary authority, such as a member of the executive team, a senior management position or an employee with financial management responsibilities. The Company shall make reasonable inquiries into the background of each individual who is a candidate for such a position. All such inquiries shall be made in accordance with applicable law and good business practice.

- **Access to the Code.** The Company shall ensure that employees, officers and directors may access the Code on the Company's website. In addition, each current employee will be provided with a copy of the Code. New employees will receive a copy of the Code as part of their new hire information. From time to time, the Company will sponsor employee training meetings in which the Code and other Company policies and procedures will be discussed.
- **Auditing.** The Nominating and Corporate Governance Committee will be responsible for auditing the Company's compliance with the Code.
- **Internal Investigation.** When an alleged violation of the Code is reported, the Company shall take prompt and appropriate action in accordance with the law and regulations and otherwise consistent with good business practice. If the suspected violation appears to involve either a possible violation of law or an issue of significant corporate interest, or if the report involves a complaint or concern of any person, whether employee, a shareholder or other interested person regarding the Company's financial disclosure, internal accounting controls, questionable auditing or accounting matters or practices or other issues relating to the Company's accounting or auditing, then the employee should immediately inform our CFO. If a suspected violation involves any director or executive officer or if the suspected violation concerns any fraud, whether or not material, involving management or other employees who have a significant role in the Company's internal controls, the person who received such report should immediately report the alleged violation to the COO and/or CFO, and, in every such case, the Chairman of the Audit Committee. The Chairman of the Audit Committee shall assess the situation and determine the appropriate course of action. At a point in the process consistent with the need not to compromise the investigation, a person who is suspected of a violation shall be apprised of the alleged violation and shall have an opportunity to provide a response to the investigator.
- **Disciplinary Actions.** Subject to the following sentence, the COO shall be responsible for implementing the appropriate disciplinary action in accordance with the Company's policies and procedures for any employee who is found to have violated the Code. If a violation has been reported to the Audit Committee or another committee of the Board, that Committee shall be responsible for determining appropriate disciplinary action, in consultation with the COO, if appropriate. Any violation of applicable law or any deviation from the standards embodied in this Code will result in disciplinary action, up to and including termination of employment. Any employee engaged in the exercise of substantial discretionary authority, including any Senior Officer, who is found to have engaged in a violation of law or unethical conduct in connection with the performance of his or her duties for the Company, shall be removed from his or her position and not assigned to any other position involving the exercise of substantial discretionary authority. In addition to imposing discipline upon employees involved in non-compliant conduct, the Company also will impose discipline, as appropriate, upon an employee's supervisor, if any, who directs or approves such employees' improper actions, or is aware of those actions but does not act appropriately to correct them, and upon other individuals who fail to report known non-compliant conduct. In addition to imposing its own discipline, the Company will bring any violations of law to the attention of appropriate law enforcement personnel.
- **Retention of Reports and Complaints.** All reports and complaints made to or received by the COO, CFO or the Chair of the Audit Committee shall be logged into a record maintained for this purpose and this record of such report shall be retained for five (5) years.
- **Required Government Reporting.** Whenever conduct occurs that requires a report to the government, the COO shall be responsible for complying with such reporting requirements.
- **Corrective Actions.** Subject to the following sentence, in the event of a violation of the Code, the COO, in consultation with the Audit Committee, should assess the situation to determine whether the violation demonstrates a problem that requires remedial action as to Company policies and procedures. If a violation has been reported to the Audit Committee or another committee of the Board, that committee shall be responsible for determining appropriate remedial or corrective actions. Such corrective action may include providing revised public disclosure, retraining Company employees, modifying Company policies and

procedures, improving monitoring of compliance under existing procedures and other action necessary to detect similar non-compliant conduct and prevent it from occurring in the future. Such corrective action shall be documented, as appropriate.

Publication of the Code of Business Conduct and Ethics; Amendments and Waivers of the Code of Business Conduct and Ethics

The most current version of this Code will be posted and maintained on the Company's website and filed as an exhibit to the Company's Annual Report on Form 10-K. The Company's Annual Report on Form 10-K shall disclose that the Code is maintained on the website and shall disclose that substantive amendments and waivers will also be posted on the company's website.

Any substantive amendment or waiver of this Code (i.e., a material departure from the requirements of any provision) particularly applicable to or directed at executive officers or directors may be made only after approval by the Board of Directors and will be disclosed within five (5) business days of such action (a) on the Company's website for a period of not less than twelve (12) months and (b) in a Form 8-K filed with the Securities and Exchange Commission. Such disclosure shall include the reasons for any waiver. The Company shall retain the disclosure relating to any such amendment or waiver for not less than five (5) years.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the registration statements on Form S-8 (Registration Nos. 333-98245, 333-48088 and 333-103129 and 333-118729) and Form S-3 (Registration Nos. 333-76234, 333-103130, 333-109584, 333-112489, 333-114441 and 333-116080) of our report dated March 9, 2005 (with respect to Notes A and J[5], March 11, 2005) on our audit of the financial statements included in the 2004 annual report on Form 10-K of Axonyx Inc. We also consent to the reference to our firm in the "Experts" sections of the registration statements on Form S-3.

Eisner LLP

New York, New York
March 15, 2005

CERTIFICATE OF CHIEF EXECUTIVE OFFICER

I, Gosse B. Bruinsma, certify that:

1. I have reviewed this annual report on Form 10-K of Axonyx 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 registrant as of, and for, the periods presented in this report;
4. The registrant'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 registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

/s/ GOSSE B. BRUINSMA

Gosse B. Bruinsma
Chief Executive Officer
Date: March 16, 2005

CERTIFICATE OF CHIEF FINANCIAL OFFICER

I, S. Colin Neill, certify that:

1. I have reviewed this annual report on Form 10-K of Axonyx 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 registrant as of, and for, the periods presented in this report;
4. The registrant'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 registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

/s/ S. COLIN NEILL

S. Colin Neill
Chief Financial Officer
Date: March 16, 2005

AXONYX INC.
SECTION 1350 CERTIFICATIONS

In connection with the periodic report of AXONYX INC., a Nevada corporation (the "Company"), on Form 10-K for the period ended December 31, 2004, as filed with the Securities and Exchange Commission (the "Report"), I, GOSSE B. BRUINSMA, Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, 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 results 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.

Date: March 16, 2005

By: /s/ GOSSE B. BRUINSMA

Gosse B. Bruinsma

In connection with the periodic report of AXONYX INC., a Nevada corporation (the "Company"), on Form 10-K for the period ended December 31, 2004, as filed with the Securities and Exchange Commission (the "Report"), I, S. COLIN NEILL, Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, 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 results 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.

Date: March 16, 2005

By: /s/ S. COLIN NEILL

S. Colin Neill

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging or otherwise adopting the signatures that appear in typed form within the electronic version of this written statement required by Section 906, has been provided to Axonyx Inc. and will be retained by Axonyx Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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

**FORM 10-K/A
(Amendment No. 1)**

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: 000-25571

AXONYX INC.

500 Seventh Avenue, 10th Floor
New York, New York 10018
Telephone (212) 645-7704

I.R.S. Employer Identification Number: 86-0883978

State or Other jurisdiction of Incorporation or Organization: NEVADA

Securities registered under Section 12(g) of the Exchange Act: COMMON STOCK \$0.001 PAR VALUE

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

The registrant estimates that the aggregate market value of its Common Stock on June 30, 2004, based on the closing price shown on the Nasdaq SmallCap Market on that date of \$5.24, held by its non-affiliates was approximately \$255,400,189.

The number of shares of Common Stock, par value \$0.001, of the Registrant outstanding as of March 22, 2005, was 53,665,518 shares.

DOCUMENTS INCORPORATED BY REFERENCE: NONE.

EXPLANATORY NOTE

Axonyx Inc. is filing this amendment to Form 10-K for the year ended December 31, 2004, filed with the Securities and Exchange Commission on March 16, 2005 (the "Original Filing"), in accordance with the Commission's Exemptive Order #34-50754, to:

- amend and restate Item 9A to include Management's Annual Report on Internal Control Over Financial Reporting;
- include a Report of Independent Registered Public Accounting Firm relating to our internal control over financial reporting; and
- include a revised Consent of Independent Registered Public Accounting Firm required as a result of the revisions discussed above.

As a result of these amendments, the certifications pursuant to Section 302 and Section 906 of the Sarbanes-Oxley Act of 2002, filed as exhibits to the Original Filing, have been re-executed and re-filed as of the date of this Form 10-K/A.

Except for the amendments described above, this Form 10-K/A does not modify or update other disclosures in, or exhibits to, the Original Filing.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this annual Report on Form 10-K, as amended on Form 10-K/A. Based on this evaluation, our principal executive officer and principal financial officer concluded that these disclosure controls and procedures are effective and designed to ensure that the information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the requisite time periods. Our management's conclusion does not take into account, and our management has not made any evaluation of, any disclosure controls and procedures of OXIS International, Inc., in which we acquired a 52% interest in January 2004 (our interest at December 31, 2004 had been reduced to 34% due an equity issuance by OXIS). The consolidated financial statements of our company as of December 31, 2004 and for the year then ended include \$2,275,000 of OXIS revenue, \$1,886,000 of OXIS net loss (excluding \$722,000 of amortization recorded in consolidation) and \$8,596,000 of total OXIS assets (excluding \$6,807,000 of an intangible asset recorded in consolidation).

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. 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 or deviations, if any within the company have been detected. While we believe that our disclosure controls and procedures have been effective, in light of the foregoing, we intend to continue to examine and refine our disclosure control and procedures to monitor ongoing developments in this area.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting and for assessing its continuing effectiveness.

Our management, including our principal executive officer and principal financial officer, has conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on such evaluation, our management has concluded that our company maintained effective internal control over financial reporting as of December 31, 2004. Our management's conclusion does not take into account, and our management has not made any evaluation of, any internal control over financial reporting of OXIS International, Inc., in which we acquired a 52% interest in January 2004 (our interest at December 31, 2004 had been reduced to 34% due an equity issuance by OXIS). The consolidated financial statements of our company as of December 31, 2004 and for the year then ended include \$2,275,000 of OXIS revenue, \$1,886,000 of OXIS net loss (excluding \$722,000 of amortization recorded in consolidation) and \$8,596,000 of total OXIS assets (excluding \$6,807,000 of an intangible asset recorded in consolidation).

Eisner LLP, our independent auditors, has issued an attestation report on management's assessment of our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

The attestation report of Eisner LLP, our independent auditors, on management's assessment of our internal control over financial reporting is contained in their Report of Independent Registered Public Accounting Firm included in this amended Annual Report on Form 10-K/A.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended) identified in connection with the evaluation of our internal control performed during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Axonyx, Inc.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting, that Axonyx, Inc. (the "Company") maintained effective internal control over financial reporting as of December 31, 2004, based on, criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Axonyx, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Axonyx, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on, criteria established in Internal Control — Integrated Framework issued by the COSO. Also, in our opinion, Axonyx, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on, criteria established in Internal Control — Integrated Framework issued by COSO.

As described in Management's Annual Report on Internal Control Over Financial Reporting, management has excluded Oxis International, Inc. ("Oxis") from its evaluation of the effectiveness of internal control over financial reporting as of December 31, 2004. Such exclusion results from the Company's acquisition of a 52% interest in Oxis during 2004 (which was reduced to 34% as of December 31, 2004 due to equity issuances by Oxis). We have also excluded Oxis from our audit of the Company's internal control over financial reporting. The consolidated financial statements of Axonyx, Inc. as of December 31, 2004 and for the year then ended include \$2,275,000 of Oxis revenue, \$1,886,000 of Oxis net loss (excluding \$722,000 of amortization recorded in consolidation) and \$8,596,000 of total Oxis assets (excluding \$6,807,000 of an intangible asset recorded in consolidation).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Axonyx, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004, and our report dated March 9, 2005 (with respect to Notes A and J[5], March 11, 2005) expressed an unqualified opinion on those consolidated financial statements.

EISNER LLP
New York, New York
March 28, 2005

Item 15. Exhibits and Financial Statement Schedules

Consolidated Financial Statements (previously filed with Form 10-K):

Report of Independent Registered Public Accounting Firm

Balance sheets as of December 31, 2004 and 2003

Statements of operations for each of the years in the three-year period ended December 31, 2004

Statements of changes in stockholders' equity for each of the years in the three-year period ended December 31, 2004

Statements of cash flows for each of the years in the three-year period ended December 31, 2004

Notes to consolidated financial statements

Exhibits:

- 2.1 Agreement of Merger between Axonyx Inc. and Ionosphere, Inc. dated December 23, 1998 (Incorporated by reference to the corresponding exhibit to the Registration Statement on Form 10-SB previously filed by Axonyx on March 17, 1999 (File No. 000-25571) (the "March 17, 1999 10-SB"))
- 2.2 Articles of Merger (Delaware) dated December 28, 1998 and Certificate of Correction dated March 10, 1999 (Incorporated by reference to the corresponding exhibit to the March 17, 1999 10-SB)
- 2.3 Articles of Merger (Nevada) dated December 28, 1998 (Incorporated by reference to the corresponding exhibit to the March 17, 1999 10-SB)
- 3.1 Restated Articles of Incorporation dated June 23, 2000 (Incorporated by reference to exhibit number 3.0(i) to the Quarterly Report on Form 10-QSB previously filed by Axonyx on August 14, 2000)
- 3.2 By-Laws (Incorporated by reference to the corresponding exhibit to the March 17, 1999 10-SB)
- 3.3 Certificate of Amendment of Restated Articles of Incorporation dated June 28, 2004 (incorporated by reference to Exhibit 3(a) in the quarterly report on Form 10-Q previously filed by Axonyx Inc. for the quarter ended June 30, 2004)
- 4.1 Form of Common Stock Purchase Warrant AXB (Incorporated by reference to exhibit 4.3 to the Annual Report on Form 10-KSB previously filed by Axonyx on March 13, 2000 (the "March 13, 2000 10-KSB"))
- 4.2 Form of Registration Rights Agreement 1999 (Incorporated by reference to exhibit 4.4 to the March 13, 2000 10-KSB)
- 4.3 Form of Warrant (Stonegate Securities) (Incorporated by reference to the corresponding exhibit to the Annual Report on Form 10-KSB previously filed by Axonyx on March 22, 2001 (the "March 22, 2001 10-KSB"))
- 4.4 Form of Common Stock Purchase Warrant AXC (Incorporated by reference to exhibit 10.2 to the Current Report on Form 8-K previously filed by Axonyx on December 13, 2001 (the "December 13, 2001 8-K"))
- 4.5 Form of Warrant (SCO Financial Group) (Incorporated by reference to the corresponding exhibit to the Registration Statement on Form S-3 previously filed by Axonyx on January 3, 2002 (File No. 333-76234))
- 4.6 Form of Common Stock Purchase Warrant [AXD](Incorporated by reference to Exhibit 10.2 in the Form 8-K previously filed by Axonyx on January 8, 2003 (File no. 00025571))
- 4.8 Form of Warrant (AFO Advisors, LLC) (Incorporated by reference to Exhibit 4.2 in the registration statement on Form S-3 previously filed by Axonyx on February 12, 2003 (File No. 333-103130))
- 4.9 Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 10.2 in the current report on Form 8-K previously filed by Axonyx on September 16, 2004 (File No. 00025571))

- 4.10 Form of Warrant (Incorporated by reference to Exhibit 4.3 in the current report on Form 8-K previously filed by Axonyx on January 12, 2004 (File No. 00025571))
- 4.11 Registration Rights Agreement dated as of January 8, 2004 between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.2 in the current report on Form 8-K previously filed by Axonyx Inc. on January 12, 2004)
- 4.12 Registration Rights Agreement dated as of May 3, 2004, between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.2 in the current report on Form 8-K previously filed by Axonyx Inc. on May 5, 2004)
- 10.1 1998 Stock Option Plan (Incorporated by reference to the corresponding exhibit to the March 17, 1999 10-SB)
- 10.2(a) 2000 Stock Option Plan (Incorporated by reference to exhibit 99.2 to the Registration on Form S-8 previously filed by Axonyx on October 17, 2000 (file number 333-48088))
- 10.2(b) First Amendment to 2000 Stock Option Plan (Incorporated by reference to the corresponding exhibit to Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.2(c) Second Amended and Restated 2000 Stock Option Plan (Incorporated by reference to Appendix E to Schedule 14A previously filed by the Company on May 14, 2004)
- 10.3(a) Patent License Agreement — Exclusive between the Public Health Service and CURE, LLC dated January 31, 1997 (Incorporated by reference to exhibit 10.2 to the Registration Statement on Form 10-SB Amendment No. 1 previously filed by Axonyx on August 10, 1999 (File no. 000-25571) (the “August 10, 1999 10-SB/A”))
- 10.3(b) License Agreement between the Axonyx Inc. and CURE, LLC dated February 27, 1997 (Incorporated by reference to exhibit 10.2 to the March 17, 1999 10-SB)
- 10.3(c) Letter Amendment of License Agreement between Axonyx Inc. and CURE, LLC dated May 27, 2002 (Incorporated by reference to exhibit 10.1 to Form 10-Q previously filed on August 14, 2002 (File No. 000-25571))
- 10.4 Research and License Agreement between the Axonyx Inc. and New York University dated April 1, 1997 (Incorporated by reference to exhibit 10.3 to the March 17, 1999 10-SB)
- 10.5 Second Amendment to Research and License Agreement between Axonyx Inc. and New York University dated March 19, 1999 (Incorporated by reference to exhibit A to the Quarterly Report on Form 10-Q previously filed by Axonyx on June 30, 1999)
- 10.6 Fourth Amendment to Research and License Agreement between Axonyx Inc. and New York University dated October 11, 2002 (Incorporated by reference to exhibit 10.1 to Form 10-Q previously filed on November 14, 2002 (File No. 000-25571))
- 10.7 Financial Consulting Agreement between Axonyx Inc. and Intertrend Management, Ltd. dated November 6, 1998 (Incorporated by reference to exhibit 10.7 in the August 10, 1999 10-SB/A)
- 10.8 Development Agreement and Right to License between Axonyx Inc. and Applied Research Systems ARS Holding N.V. dated May 17, 1999 (Incorporated by reference to exhibit 99(c) to the Current Report on Form 8-K previously filed by Axonyx on June 1, 1999)
- 10.9 License Agreement between Axonyx Inc. and Applied Research Systems ARS N.V. dated September 15, 2000 (Incorporated by reference to exhibit 10.9 to the March 22, 2001 10-KSB)
- 10.10 Sponsored Research Agreement between the University of Melbourne and Axonyx Inc. dated October 1, 1999 (Incorporated by reference to exhibit 10.10 to the March 22, 2001 10-KSB)
- 10.11 Common Stock Underwriting Agreement between Ramius Securities, LLC and Axonyx Inc. dated October 25, 2000 (Incorporated by reference to exhibit 10.11 to the March 22, 2001 10-KSB)
- 10.12 Stand-By Purchase Agreement between Ramius Capital Group, LLC and Axonyx Inc. dated October 25, 2000 (Incorporated by reference to exhibit 10.12 to the March 22, 2001 10-KSB)

- 10.13 Lease Agreement between Axonyx Inc. and Business Service Center of Seattle dated January 28, 1999 (Incorporated by reference to exhibit 10.5 to the March 17, 1999 10-SB)
- 10.14 Occupancy Agreement between Axonyx Inc., J.A. Bernstein & Co. and The Garnet Group, Inc. dated December 14, 1999 (Incorporated by reference to exhibit 10.10 to the March 13, 2000 10-KSB)
- 10.15 Letter Agreement between Axonyx Inc. and J.A. Bernstein & Co. dated December 9, 1999 (Incorporated by reference to exhibit 10.11 to the March 13, 2000 10-KSB)
- 10.16 Data Management and Reporting Services Agreement between Axonyx Inc. and Clinfo Systems, LLC dated October 2, 2000 (Incorporated by reference to the corresponding exhibit to the Annual Report on Form 10-KSB Amendment No. 1 previously filed by Axonyx on May 15, 2001 (the "May 15, 2001 10-KSB/A"))
- 10.17 Data Management and Reporting Services Agreement between Axonyx Inc. and Clinfo Systems, LLC dated January 2, 2001 (Incorporated by reference to the corresponding exhibit to the May 15, 2001 10-KSB/A)
- 10.18† Research Agreement between Thomas Jefferson University and Axonyx Inc. dated as of April 1, 2001 (Incorporated by reference to exhibit 10.1 to the Quarterly Report on Form 10-Q previously filed by Axonyx on May 15, 2001)
- 10.19 Sponsored Research Agreement and Option between Mayo Foundation for Medical Education and Research, Mayo Clinic Jacksonville and Axonyx Inc. dated May 1, 2001 (Incorporated by reference to the corresponding exhibit to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.20 Research Agreement between Indiana University and Axonyx Inc. dated August 15, 2001 (Incorporated by reference to the corresponding exhibit to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.21 Common Stock and Warrant Purchase Agreement dated December 4, 2001 (Incorporated by reference to exhibit 10.1 to the December 13, 2001 8-K)
- 10.22** Employment Agreement by and between Axonyx Europe B.V. and Dr. Gosse Bruinsma dated October 10, 2000 (Incorporated by reference to exhibit 10.22 to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.23** Letter Agreement between Axonyx Inc. and Dr. Robert Burford dated November 10, 1999 (Incorporated by reference to exhibit 10.23 to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.24 Research Agreement between David Henry Small, Ph.D. and Axonyx Inc. dated September 1, 2002 (Incorporated by reference to exhibit 10.2 to Form 10-Q previously filed on November 14, 2002 (File No. 000-25571))
- 10.25 Intellectual Property Assignment Agreement between David Henry Small, Ph.D., Marie-Isabel Aguilar, Ph.D., Supundi Subasinghe and Axonyx Inc. dated September 1, 2002 (Incorporated by reference to exhibit 10.3 to Form 10-Q previously filed on November 14, 2002 (File No. 000-25571))
- 10.26 Common Stock and Warrant Purchase Agreement dated as of December 31, 2002 (Incorporated by reference to Exhibit 10.1 in the Form 8-K previously filed by Axonyx on January 8, 2003 (File No. 00025571))
- 10.27 Clinical Trial Services Master Agreement between JSW Research and Axonyx Inc. dated March 21, 2003 (Incorporated by reference to Exhibit 10.27 in the Form 10-K previously filed by Axonyx on March 31, 2003 (File No. 00025571))
- 10.28 Contract between Axonyx Europe and NOTOX Safety and Environmental Research B.V. dated April 11, 2002 (Incorporated by reference to Exhibit 10.28 in the Form 10-K previously filed by Axonyx on March 31, 2003 (File No. 00025571))
- 10.29 Common Stock and Warrant Purchase Agreement dated as of September 11, 2003 (Incorporated by reference to Exhibit 10.1 in the current report on Form 8-K previously filed by Axonyx on September 16, 2004 (File No. 00025571))

- 10.30 Securities Purchase Agreement dated as of January 8, 2004 (Incorporated by reference to Exhibit 4.1 in the current report on Form 8-K previously filed by Axonyx on January 12, 2004 (File No. 00025571))
- 10.31 Share Exchange Agreement dated as of January 15, 2004 between Axonyx Inc. and Oxis International, Inc., (incorporated by reference to Exhibit 10.1 in the current report on Form 8-K previously filed by Axonyx Inc. on January 20, 2004)
- 10.32** Change of Control Agreement dated as of March 30, 2004 between Axonyx and Marvin S. Hausman (incorporated by reference to Exhibit 10.32 of Axonyx Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2003)
- 10.33** Change of Control Agreement dated as of March 30, 2004 between Axonyx and Gosse Bruinsma (incorporated by reference to Exhibit 10.33 of Axonyx Inc. Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2003)
- 10.34** Change of Control Agreement dated as of March 30, 2004 between Axonyx and S. Colin Neill (incorporated by reference to Exhibit 10.34 of Axonyx Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2003)
- 10.35 Securities Purchase Agreement dated as of May 3, 2004 between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.1 in the current report on Form 8-K previously filed by Axonyx Inc. on May 5, 2004)
- 14 Code of Business Conduct and Ethics***
- 21 List of Subsidiaries (Incorporated by reference to the corresponding exhibit to the March 22, 2001 10-KSB)
- 23.1 Consent of Eisner LLP*
- 31.1 Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer*
- 31.2 Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer*
- 32 Section 1350 Certification of Chief Executive Officer and Chief Financial Officer*

* Filed herewith

** Indicates management compensation agreement

*** Previously filed

† Certain information omitted pursuant to a request for confidential treatment filed separately with and granted by the SEC

SIGNATURE

In accordance with Section 13 or 15(d) of the Exchange Act of 1934, as amended, the registrant caused this amended Annual Report on Form 10-K/A to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, New York on this 30th day of March, 2005.

AXONYX INC.

By: /s/ S. Colin Neill

S. Colin Neill
Chief Financial Officer

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the registration statements on Form S-8 (Registration Nos. 333-98245, 333-48088, 333-103129 and 333-118729) and Form S-3 (Registration Nos. 333-76234, 333-103130, 333-109584, 333-112489, 333-114441 and 333-116080) of our report dated March 28, 2005 on our audit of Management's Annual Report on Internal Control Over Financial Reporting and the effectiveness of internal control over financial reporting included in the 2004 annual report on Form 10-K/A of Axonyx Inc. We also consent to the reference to our firm in the "Experts" sections of the registration statements on Form S-3.

Eisner LLP
New York, New York
March 28, 2005

CERTIFICATE OF CHIEF EXECUTIVE OFFICER

I, Gosse B. Bruinsma, certify that:

1. I have reviewed this annual report on Form 10-K, as amended on Form 10-K/A, of Axonyx 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 registrant as of, and for, the periods presented in this report;
4. The registrant'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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant'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
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

/s/ GOSSE B. BRUINSMA

Gosse B. Bruinsma
Chief Executive Officer
Date: March 30, 2005

CERTIFICATE OF CHIEF FINANCIAL OFFICER

I, S. Colin Neill, certify that:

1. I have reviewed this annual report on Form 10-K, as amended on Form 10-K/A, of Axonyx 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 registrant as of, and for, the periods presented in this report;
4. The registrant'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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant'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
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

/s/ S. COLIN NEILL

S. Colin Neill
Chief Financial Officer
Date: March 30, 2005

AXONYX INC.
SECTION 1350 CERTIFICATIONS

In connection with the periodic report of AXONYX INC., a Nevada corporation (the "Company"), on Form 10-K, and as amended on Form 10-K/A, for the period ended December 31, 2004, as filed with the Securities and Exchange Commission (the "Report"), I, GOSSE B. BRUINSMA, Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, 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 results 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.

Date: March 30, 2005

By: /s/ GOSSE B. BRUINSMA

Gosse B. Bruinsma

In connection with the periodic report of AXONYX INC., a Nevada corporation (the "Company"), on Form 10-K, and as amended on Form 10-K/A, for the period ended December 31, 2004, as filed with the Securities and Exchange Commission (the "Report"), I, S. COLIN NEILL, Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, 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 results 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.

Date: March 30, 2005

By: /s/ S. COLIN NEILL

S. Colin Neill

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging or otherwise adopting the signatures that appear in typed form within the electronic version of this written statement required by Section 906, has been provided to Axonyx Inc. and will be retained by Axonyx Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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DIRECTORS

Marvin S. Hausman, M.D.
Chairman of the Board

Gosse B. Bruinsma, M.D.
President and Chief Executive Officer
President, Axonyx Europe BV

Louis G. Cornacchia
President, Scinetics Corporation

Steven H. Ferris, Ph.D.
Friedman Professor of the Alzheimer's
Disease Center, Dept. of Psychiatry, NYU
School of Medicine, Executive Director,
NYU's Silberstein Institute for Aging and
Dementia and Principal Investigator,
Alzheimer's Disease Center

Steven B. Ratoff
Venture Partner, Proquest Investments

Ralph Snyderman, M.D.
Chancellor Emeritus, Duke University

Gerard J. Vlak, Ph.D. *
Retired from senior executive positions at
Rabobank and ABN-AMRO Bank USA

OFFICERS

Gosse B. Bruinsma, M.D.
President and Chief Executive Officer

S. Colin Neill
Chief Financial Officer, Treasurer and
Secretary

CORPORATE INFORMATION

Corporate Office

Axonyx Inc.
500 7th Avenue
10th Floor
New York, NY 10018
212-645-7704
www.axonyx.com

* Not standing for re-election in 2005

European Subsidiary

Axonyx Europe BV
Middelstegracht 87H
2312 TT Lieden, The Netherlands
31-71-589-3463

Legal Counsel

Eilenberg & Krause LLP
11 East 44th Street
17th Floor
New York, NY 10017
212-986-9700

Patent Counsel

Trask Britt
230 South 500 East
Suite 300
Salt Lake City, UT 84102
801-532-1922

Transfer Agent

Nevada Agency and Trust
50 West Liberty Street
Suite 880
Reno, NV 89501
775-322-0626

Independent Auditors

Eisner LLP
750 Third Avenue
New York, NY 10017
212-949-8700

NASDAQ Symbol: **AXYX**

AXONYX

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