

AXONYX INC  
Form 10-K  
March 16, 2006

---

---

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, 2005

OR

TRANSACTION 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, 10<sup>th</sup> 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 pursuant to Section 12(g) of the Act: COMMON STOCK \$0.001 PAR VALUE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.  Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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 a large accelerated filer, an accelerated filer or a non-accelerated filer (as defined in Rule 12b-2 of the Act).

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes  No

The aggregate market value of the Common Stock held by non-affiliates as of June 30, 2005 (calculated using the closing price on that date on NASDAQ of \$1.33 per share) was approximately \$67,840,000.

The number of shares of Common Stock, par value \$0.001, of the Registrant outstanding as of March 15, 2006, was 53,680,721 shares.



**DOCUMENTS INCORPORATED BY REFERENCE: NONE**

**Table of Contents**

|                                    | <u>Page</u>  |
|------------------------------------|--|
| <b><u>PART I</u></b>               |  |
| <u>Item 1.</u>                     | <u>Business</u> 5  |
| <u>Item 1A.</u>                    | <u>Risk Factors</u> 19   |
| <u>Item 1B.</u>                    | <u>Unresolved Staff Comments</u> 31  |
| <u>Item 2.</u>                     | <u>Properties</u> 31   |
| <u>Item 3.</u>                     | <u>Legal Proceedings</u> 31  |
| <u>Item 4.</u>                     | <u>Submission of Matters to a Vote of Security Holders</u> 31  |
| <b><u>PART II</u></b>              |  |
| <u>Item 5.</u>                     | <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> 32 |
| <u>Item 6.</u>                     | <u>Selected Financial Data</u> 32  |
| <u>Item 7.</u>                     | <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 33                        |
| <u>Item 7A.</u>                    | <u>Quantitative and Qualitative Disclosures About Market Risk</u> 41   |
| <u>Item 8.</u>                     | <u>Financial Statements and Supplementary Data</u> 42  |
| <u>Item 9.</u>                     | <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u> 42                         |
| <u>Item 9A.</u>                    | <u>Controls and Procedures</u> 42  |
| <u>Item 9B.</u>                    | <u>Other Information</u> 44  |
| <b><u>PART III</u></b>             |  |
| <u>Item 10.</u>                    | <u>Directors and Executive Officers of the Registrant</u> 44   |
| <u>Item 11.</u>                    | <u>Executive Compensation</u> 47   |
| <u>Item 12.</u>                    | <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> 51               |
| <u>Item 13.</u>                    | <u>Certain Relationships and Related Transactions</u> 54   |
| <u>Item 14.</u>                    | <u>Principal Accountant Fees and Services</u> 54   |
| <u>Item 15.</u>                    | <u>Exhibits and Financial Statement Schedules</u> 55   |
| <b><u>SIGNATURES</u></b>           | 60   |
| <b><u>FINANCIAL STATEMENTS</u></b> | F-1  |
| <b><u>EXHIBITS</u></b>             | III-24   |

*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.*

*The statements represent our judgment to date, and are subject to risks and uncertainties that could affect the Company, including those risks and uncertainties described in the documents Axonyx files from time to time with the SEC. Specifically, with respect to our drug candidates Phenserine, Posiphen and Bisnorcymserine, Axonyx cannot assure that: any preclinical studies or clinical trials, whether ongoing or conducted in the future, will prove successful, and if successful, that the results can be replicated; safety and efficacy profiles of any of its drug candidates will be established, or if established, will remain the same, be better or worse in future clinical trials, if any; pre-clinical results related to cognition and the regulation of beta-APP will be substantiated by ongoing or future clinical trials, if any, or that any of its drug candidates will be able to improve the signs or symptoms of their respective clinical indication or slow the progression of Alzheimer's disease; any of its drug candidates will support an NDA filing, will be approved by the FDA or its equivalent, or if approved, will prove competitive in the market; or that Axonyx will have or obtain the necessary financing to support its drug development programs. Axonyx cannot assure that it will be successful with regard to identifying a (sub-)licensing partner for any of its compounds, or that any that such partner will successfully develop or commercialize any of such compounds. 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**

**TABLE OF CONTENTS**

- A. Recent Events
- B. Axonyx Business Strategy and Drug Development Programs
- C. Alzheimer's Disease Overview
- D. Out-Licensed Technology
- E. Competition
- F. Government Regulation
- G. Strategic Alliances
- H. Marketing and Sales
- I. Patents, Trademarks, and Copyrights
- J. Employees
- A. Recent Events**

**Advances and milestones with our drug development programs**

We currently have three compounds in development for Alzheimer's disease (AD): Phenserine, a potential symptomatic and disease progression treatment for mild to moderate AD; Posiphen, a potential disease progression treatment for AD; and Bisnorcymserine (BNC), a potential symptomatic treatment for severe AD. See Item 1, Section B, Axonyx Business Strategy and Drug Development Programs.

In February 2005, we announced the top line outcome of our first Phase III clinical trial with Phenserine in 375 patients exhibiting mild to moderate AD. The trial 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. The trial did not reveal any adverse events, safety or tolerability concerns. At that time we halted additional patient recruitment for the second and third Phase III clinical trials in order to evaluate the planned Phenserine clinical program following recommendations from the Company's Scientific Advisory Board and Safety Steering Committee.

In July 2005, we conducted a second interim statistical analysis of 59 patients from a then ongoing Phase IIb double-blind placebo-controlled clinical trial (AX-CL-06a). This trial was designed to evaluate the effects of Phenserine tartrate treatment for 6 months on plasma and cerebrospinal fluid (CSF) levels of beta-amyloid (A $\beta$  1-42) and other biomarkers in mild to moderate AD patients. While this second interim analysis appeared to again confirm that Phenserine could have a beneficial effect on the levels of beta-amyloid, definitive conclusions could not be drawn due to the variability of the data.

In August 2005, the U.S. Food and Drug Administration (FDA) approved our Investigational New Drug (IND) application, submitted in June 2005, allowing Phase I clinical testing of Posiphen. The first Phase I clinical study primarily evaluated the safety of single ascending doses of Posiphen in healthy volunteers.

In September 2005, we announced top line results of an analysis of the two curtailed Phase III clinical trials (AX-CL-09/010) with Phenserine. Results following 12 weeks of treatment, as measured by the AD Assessment Scale, cognitive subscale (ADAScog) and Clinical Interview Based Impression of Change with caregiver input (CIBIC+), did not demonstrate a statistically significant benefit of Phenserine treatment over placebo. Patient recruitment for these studies had previously been halted and the planned 26-week treatment period shortened based on previously released results of a 375-patient trial (AX-CL-06) [see above] which had showed no statistically significant differences between Phenserine and placebo. There were no safety or tolerability concerns associated with Phenserine treatment.



In November 2005, we announced the results of an additional analysis of a subgroup of 188 patients from the two curtailed Phase III clinical trials (AX-CL-09/010) with Phenserine. The subgroup of patients, who received Phenserine 15mg twice daily, demonstrated a statistically significant benefit over placebo as measured by ADAS-cog, when treated for more than 12 weeks. Additionally, this subgroup showed a positive trend towards improvement in CIBIC+ test, which approached statistical significance. There were no unexpected safety or tolerability concerns associated with Phenserine treatment. This analysis was undertaken in addition to the previously announced results of the primary pre-defined statistical analysis.

In January 2006, we announced that we had granted to Daewoong Pharmaceutical Company Ltd. (Daewoong) an exclusive license for the use of Phenserine in the South Korean market. Under the terms of the agreement Daewoong, at its own cost, undertakes to pursue the product development and regulatory work necessary for a New Drug Application (NDA) (or its equivalent) in South Korea with respect to Phenserine for the treatment of AD. The financial terms of the deal include royalty payments to us based on sales of Phenserine by Daewoong in the South Korean market.

In January 2006, we announced the completion of a single ascending dose Phase I trial with Posiphen, in clinical development for the treatment of AD progression. This double-blind, placebo controlled study of Posiphen in healthy men and women sought to establish well tolerated doses. Posiphen appears to be well tolerated at single doses up to and including 80mg. Blood levels of Posiphen associated with this study were higher than those associated with beneficial effects on beta-amyloid metabolism in animal models. The build-up of beta-amyloid (A $\beta$ ) is generally believed to be causative of the dementia of AD. No serious adverse events were reported at any dose level.

We announced in January of 2006 that three presentations of data on our drug development candidate, Phenserine, and one presentation of data on our drug development candidate, Posiphen, will be made at the 9th International Geneva/Springfield Symposium on Advances in Alzheimer Therapy in Geneva, Switzerland, being held April 19-22, 2006.

In February 2006, we reported a statistically significant reduction in the plasma levels of beta-amyloid 1-42 (AB-42) in healthy subjects treated with Phenserine for 35 days, in a previously conducted Phase I study.

#### **Recent Board and Management Changes**

In March of 2005 we announced that Marvin S. Hausman, MD had stepped down as Chief Executive Officer and that Gosse B. Bruinsma MD has been unanimously appointed by the Board of Directors to this position. Dr. Hausman continued to serve as Chairman of the Board. Dr. Bruinsma joined Axonyx in 2000 as President of Axonyx Europe BV based in the Netherlands. In April 2001 Dr. Bruinsma was promoted to Chief Operating Officer and in September 2003 he became our President.

In May 2005, we appointed Steven B. Ratoff to the Board of Directors. Mr. Ratoff replaced Michael A. Griffith, who resigned from the Board on April 29, 2005 in order to fully pursue a new business venture he is leading.

In June 2005, we announced that Marvin S. Hausman, MD, would step down as Chairman on September 14, 2005 but would remain a director of our board. The board of directors unanimously elected Steven B. Ratoff as non-executive Chairman to succeed Dr. Hausman.

In June 2005, we appointed Paul Feuerman as our General Counsel. Mr. Feuerman is a founding member of PharmAdvisors LLC, a consulting firm serving pharmaceutical and biopharmaceutical companies. Formerly, he was Executive Vice President and General Counsel of Schein Pharmaceutical Inc., a New York Stock Exchange listed specialty pharma/generics company.

#### **Other Recent Events**

In May of 2005, we approved the adoption of a shareholder rights plan. The shareholder rights plan was designed to ensure that shareholders realize fair value and equal treatment in the event of an attempted takeover of



the Corporation and to protect the Corporation and its shareholders against coercive takeover tactics. The plan was not adopted as a result of any existing or proposed potential takeover threat.

In December 2005 we received notice from The NASDAQ Stock Market, Inc. that the minimum bid price of the Company's common stock had fallen below \$1.00 for 30 consecutive business days and that we were therefore not in compliance with NASDAQ Marketplace Rule 4310(c)(4). On March 8, 2006 we received a letter from NASDAQ that we had regained compliance with the \$1.00 per share minimum bid price requirement for continued listing on the NASDAQ Capital Market.

## **B. Axonyx Business Strategy and Drug Development Programs**

We are a biopharmaceutical company, specializing in central nervous system (CNS) neurodegenerative diseases, engaged in the business of acquiring 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, or potentially another company with similar rights. 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 patent rights to three main classes of therapeutic compounds designed for the treatment of AD, Mild Cognitive Impairment, 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 from New York University. We also have co-ownership rights to patent applications regarding the therapeutic compound named Posiphen designed for the treatment of AD progression and Bisnorcymserine (BNC) in development for the treatment of severe AD.

Our mission is to be a leading biopharmaceutical company that develops products and technologies to treat central nervous system disorders. Our initial business strategy has been focused primarily on three compounds in development for AD. These are:

Phenserine A symptomatic and disease progression treatment of mild to moderate AD

Posiphen A disease progression treatment for AD

Bisnorcymserine (BNC) A symptomatic treatment of severe AD

Our current business strategy includes identifying and seeking to in-license potential compounds or partner with companies to expand our product development portfolio.

Phenserine is an inhibitor of acetylcholinesterase for the potential treatment of mild to moderate AD. Acetylcholinesterase is an enzyme active in the nerve synapse that degrades the neurotransmitter acetylcholine in the brain and other tissues of the body. Acetylcholinesterase inhibitors are drugs designed to selectively inhibit acetylcholinesterase. 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. Inhibition of its breakdown in AD patients has been shown to improve memory and cognition.

Posiphen is a compound that appears to decrease the formation of the beta amyloid precursor protein (beta-APP) and amyloid with potential applications in the treatment of AD progression. Posiphen is the positive isomer of Phenserine. As such, it appears to affect the messenger RNA of beta-APP as well as inhibit beta secretase whereby levels of neurotoxic beta amyloid, in preclinical animal models, are reduced.

Bisnorcymserine is a butyrylcholinesterase inhibitor. Butyrylcholinesterase is found in high concentration in the plaques taken from individuals who have died from AD. Butyrylcholinesterase is an enzyme that is normally found widely in the body and butyrylcholine appears to play a relatively increasingly important role in advancing AD. Inhibition of the enzyme may prove valuable in the treatment of severe AD.

### **The Phenserine Development Program**

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 National Institute of Aging (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 ascending doses 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. 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.

To date, we have conducted the following Phase III clinical trials with Phenserine: AX-CL-06/06e, AX-CL-09, AX-CL-010, as well as a Phase IIb trial, AX-CL-06a.

Protocol AX-CL-06 was a double-blind, placebo controlled trial initiated in June 2003 comparing the efficacy and tolerability of Phenserine 10mg or 15mg twice daily doses with twice daily placebo in patients who met the diagnostic criteria for probable mild to moderate AD. Two different regimens, 10mg twice daily and 15mg twice daily, were compared with placebo in this trial. The randomization was 1:2:2 for placebo: 10mg twice daily: 15mg twice daily. Patients randomized to active treatment were started on a 5mg twice daily regimen for the first month of treatment. This was increased to 10mg twice daily for the second month of treatment. The dose was increased to 15mg twice daily during the third month for patients randomized to the highest dose regimen. Once a patient reached his or her target dose, it was maintained for a total treatment duration of 26 weeks. Patients who could not tolerate their target dose were discontinued. Discontinued patients were not replaced. A total of 384 patients were enrolled in the study. Of these, 377 received treatment. The remaining 7 never received drug treatment so they were excluded from the data analyses.

The primary efficacy variables were the ADAS-Cog and CIBIC+. The Phenserine groups showed consistently greater improvement in ADAS-Cog and CIBIC+ scores than the placebo group although the differences did not achieve statistical significance.

Protocol AX-CL-06a was a double-blind placebo controlled study of the effect of Phenserine 10- or 15mg twice daily on cerebrospinal and plasma amyloid peptides from baseline and, at 26 weeks, initiated in June 2003. Although both doses of Phenserine tended to lower beta amyloid peptides more than placebo, none of the differences achieved statistical significance.

Protocol AX-CL-06e was an open-label extension to studies AX-CL-06 and AX-CL-06a that allowed all patients who had successfully completed either trial to continue on Phenserine 15mg twice daily dose for up to an additional six months. This extension was to gather additional safety data on Phenserine treatment.

Protocol AX-CL-09/010, initiated in the second half of 2004, was originally initiated as two identical 26-week placebo controlled trials of 450 AD patients each. During the implementation of the studies, results of Protocol AX-CL-06 became available. The results of this earlier study showed a numerical benefit of Phenserine treatment relative to placebo but failed to achieve statistical significance. Based on these results, enrollment in the two ongoing studies was halted at 255 patients in total, and the primary endpoint analysis was shortened to 12 weeks. Because the individual curtailed studies were underpowered, their data were combined and analyzed as a single trial. This was a randomized, multinational, multicenter placebo-controlled parallel-group study. Because the study was curtailed, many patients did not reach the originally scheduled 26-week end of treatment. However, all patients were allowed to complete at least 12 weeks of therapy. Patients were screened within 21 days of entry and randomly assigned to receive 10 or 15 mg of Phenserine twice daily or placebo. A titration schedule was used so that patients randomized to active treatment received 5mg twice daily for the first 4 weeks of the study followed by 10mg twice daily for 4 weeks. Patients randomized to 15mg twice daily received this dose starting in the ninth week. Treatment at the assigned doses was continued for up to 26 weeks. At the 12-week visit, patients randomized to 10mg twice daily had received this dose for approximately 8 weeks. Patients randomized to receive 15mg twice daily had received this dose for approximately 4 weeks.

Although the study did not achieve statistical significance in its primary endpoints, a subgroup of patients, who received Phenserine 15mg twice daily, demonstrated a statistically significant benefit over placebo as measured by the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog), when treated for more than 12 weeks. Additionally, this subgroup showed a positive trend towards improvement in the Clinical Interview Based Impression of Change (CIBIC+) test, which approached statistical significance. There were no unexpected safety or tolerability concerns associated with Phenserine treatment.

We have comprehensive data sets on Phenserine having completed extensive manufacturing scale-up, preclinical studies and taken the drug into three Phase III clinical trials for mild to moderate AD. The remaining work to be done prior to an NDA submission for Phenserine is the completion of two pivotal Phase III trials. The Company has determined that it will not commit further resources to these Phase III trials, and is seeking to identify strategic partners that are able and willing to commit the necessary financial resources to Phenserine's further development and marketing approval.

In January 2006, we announced that we had granted to Daewoong Pharmaceutical Company Ltd. (Daewoong) an exclusive license for the use of Phenserine in the South Korean market. Under the terms of the agreement Daewoong, at its own costs, undertakes to pursue the product development and regulatory work necessary for a New Drug Application (NDA) (or its equivalent) in South Korea with respect to Phenserine for the treatment of AD. The financial terms of the deal include royalty payments to us based on sales of Phenserine by Daewoong in the South Korean market.

### **The Posiphen Development Program**

Posiphen is the positive isomer of Phenserine. It appears to decrease the formation of beta-amyloid with potential application in the treatment of AD progression. Posiphen's mechanism of action is potentially through RNA translational inhibition as well as beta secretase inhibition. Posiphen has been shown to lower beta amyloid precursor protein (beta-APP) and beta-amyloid levels in pre-clinical studies. The primary mechanism of action

results in a dose dependent reduction of beta-amyloid, which may result in slowing AD progression. The initial pre-clinical side effect rates potentially allow for higher clinical doses. On August 1, 2005 we announced that the US Food and Drug Administration (FDA) approved our investigational new drug (IND) application allowing Phase I clinical testing of Posiphen . The first Phase I single ascending dose clinical study commenced in August 2005 and evaluated the safety of Posiphen in healthy volunteers.

In January 2006, we completed a single ascending dose Phase I trial with Posiphen . This double-blind, placebo controlled study of Posiphen in healthy men and women sought to establish well tolerated doses. Posiphen appears to be well tolerated at single doses up to and including 80mg. Blood levels of Posiphen associated with this study were higher than those associated with beneficial effects on beta-amyloid metabolism in animal models. The build-up of beta-amyloid ( $A\beta$ ) is generally believed to be causative of the dementia of AD. No serious adverse events were reported at any dose level. We anticipate initiating a Phase I multiple ascending dose study in the first quarter of 2006.

### **The Bisnorcymserine Development Program**

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, potentially 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 butyrylcholinesterase inhibitor drug candidates, including 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. It 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.

Bisnorcymserine (BNC) is a highly selective butyrylcholinesterase inhibitor. Butyrylcholinesterase is found in high concentration in the plaques taken from individuals who have died from AD. Butyrylcholinesterase appears to have an increasing role with advancing AD and its primary mechanism of action results in a dose dependent reduction of acetylcholine. The initial pre-clinical side effect rate potentially allows higher clinical doses. A secondary mechanism of action is associated with dose dependent reductions of beta APP and amyloid beta. BNC, the lead compound from our butyrylcholinesterase family, is currently in full pre-IND development and we plan an IND submission in second quarter 2006 followed by the potential to initiate Phase I clinical trials thereafter. A recently published article in the Proceedings of the National Academy of Science describes the underlying mechanism, in vitro and cognition results in animal models.

### **Other Acetylcholinesterase Inhibitors**

We have assessed certain properties of our other inhibitors of acetylcholinesterase such as Tolserine, which 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.

### **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 Pertinent Information**

In December 2000, we 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. To date the majority of our clinical development activities and a significant amount of our pre-clinical development activities have been 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 our licensed technologies and facilitates communication with our European shareholders.

We have incurred negative cash flows from operations since our inception in 1997. Our net losses for the three fiscal years ended 2003, 2004 and 2005 were \$8,106,000, \$28,780,000 and \$28,614,000, respectively.

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

## **C. Alzheimer's Disease Overview**

### **Axonyx Drug Development Programs**

We are currently focusing on the development for Posiphen, a potential disease progression treatment for AD; and Bisnorcymserine (BNC), a potential symptomatic treatment for severe AD. We are seeking a licensing partner for our lead acetylcholinesterase inhibitor, Phenserine. See Item 1, Section B Axonyx Business Strategy and Drug Development Programs. In addition, we are sponsoring basic research at the medical University of South Carolina and the University of Indiana in the area of amyloid production and metabolism.

### **General**

AD 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 neurotoxic beta amyloid and 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.

AD 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.

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.

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 our 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. Our 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.

#### **D. Out-Licensed Technology**

Under 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, we granted to ARS a sublicense of our patent rights and know-how regarding the development and marketing of the Amyloid Inhibitory Peptide (AIPs) and the Prion Inhibitory Peptide (PIPs) technology which had been licensed to us under a Research and License Agreement with New York University. See Item 1, Section G Business, Strategic Alliances. We are negotiating a re-acquisition of those rights from ARS and an option to license, on a non-exclusive basis, certain Serono patents, technology and know-how related to AIPs and PIPs. If we exercise this option and acquire the license, we would be obligated to pay to Serono an upfront payment and under certain circumstances additional milestone payments and royalties would be due.

In January 2006, we announced that we had granted to Daewoong Pharmaceutical Company Ltd. (Daewoong) an exclusive license for the use of Phenserine in the South Korean market. Under the terms of the agreement Daewoong, at its own cost, undertakes to pursue the product development and regulatory work necessary for a New Drug Application (NDA) (or its equivalent) in South Korea with respect to Phenserine for the treatment of AD. The financial terms of the deal include royalty payments to us based on sales of Phenserine by Daewoong in the South Korean market.

#### **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 AD. 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<sup>®</sup> (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.

Several biotechnology companies have drugs in clinical trials that are based on a beta-amyloid approach to the treatment of AD. In addition, other small biotechnology companies appear to be pursuing studies on the amyloid inhibitory peptide approach similar in scope and direction as that we had sub-licensed to 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.

#### **G. Strategic Alliances**

##### **Background: Amyloid Inhibitory Peptides (AIPs) and Prion Inhibitory Peptides (PIPs)**

In AD 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 AD.



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 New York University (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.

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.

#### **New York University License**

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 AD 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 provisions 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 we 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. Axonyx had sublicensed the technology covered by the Research and License Agreement to ARS, a wholly owned subsidiary of Serono International, S.A.. We are negotiating a reacquisition of those rights from ARS. See Item 1, Business, Outlicensed Technology, Section D.

#### **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 is 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 (November 2013 in Europe, extendable to November 2018 under EU Regulation (EEC) 1768/92).

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. We are negotiating a further amendment of those provisions and dates.

## **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 patents, proprietary rights, and operate without infringing on the proprietary rights of third parties. Our policy is to file and/or prosecute patent applications to protect technology, inventions, and improvements that we consider important to our business and operations. We or our licensors or collaborators have filed patent applications on products and processes relating to our lead compounds, Phenserine, Posiphen, and Bisnorcymserine (BNC), as well as other technologies and inventions in the United States and in certain foreign countries. We intend to file additional patent applications, when appropriate, relating to improvements in these technologies and other specific products and processes. We plan to vigorously prosecute, enforce, and defend our patents and other proprietary technology, although we recognize that the scope and validity of patents is never certain. Obtaining and maintaining our patent position is costly. We pay for the filing, prosecution and maintenance of over 150 patents and patent applications in countries around the world, including the United States, Europe, Japan, Canada, Australia, New Zealand and South Korea. In the United States alone, Axonyx has rights in ten issued patents.

In February of 1997, CURE LLC granted us an exclusive license to certain patents and patent applications relating to the development and commercialization of Phenserine. Under this license agreement we have to achieve specified benchmarks and upon receipt of marketing approval for Phenserine, to pay royalties based on the net sales. This license terminates upon expiration of the last to expire of the licensed patents (September 2011 in the United States, extendable through 2016 under the Patent Term Restoration Act of 1984).

Axonyx and the NIH jointly own rights in patent applications directed to the use of Posiphen to reduce  $\beta$ -amyloid protein levels and treat the underlying pathology of AD. These patents expire in March of 2022.

Axonyx and the NIH jointly own rights in issued patents and patent applications directed to butyrylcholinesterase inhibitors, including BNC, and methods of treating cognitive disorders. These patents expire in July of 2018.

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.

Others may independently develop similar products or processes to those developed by us, and design around any products and processes covered by our patents. Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued to or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties.

In April of 1997, New York University (NYU) granted us an exclusive license to certain patents and patent applications. Pursuant to an Intellectual Property Agreement, an additional patent application in this technology was assigned to us. These patents and patent applications relate to beta-breaker peptide analogs capable of inhibiting the formation of amyloid or amyloid-like deposits (AIPs and PIPs). We sublicensed this technology to a subsidiary of Serono International, S.A. See Item 1, Section D, Business, Out-licensed Technology.

We filed a U.S. trademark application for POSIPHEN filed foreign trademark applications.

We have not filed for any copyright protection to date.

## J. Employees

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

**Item 1A. Risk Factors.**

**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 Form 10K 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 had clinical trial failures on our lead compound.**

We have not achieved statistical significance in the primary endpoints in the Phase III trials conducted to date with our lead compound, Phenserine. We are seeking a partner to continue the development of Phenserine, including conducting additional Phase III trials. These trials are costly. We cannot assure that we will be able to successfully conclude a deal with a partner. If we do find a partner to continue developing Phenserine, we cannot assure that they will successfully develop or commercialize Phenserine.

**We are a defendant in a class action lawsuit and a shareholder derivative lawsuit which, if determined adversely, could have a material adverse affect on us.**

A class action securities lawsuit and a shareholder derivative lawsuit have been filed against us as described under Item 3 Legal Proceedings. We are defending 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. The uncertainty associated with substantial unresolved lawsuits could harm our business, financial condition and reputation.

We have certain obligations to indemnify our officers and directors and to advance expenses to such officers and directors. Although we have purchased liability insurance for our directors and officers, if our insurance carriers should deny coverage, or if the indemnification costs exceed the insurance coverage, we may be forced to bear some or all of these indemnification costs directly, which could be substantial and may have an adverse effect on our business, financial condition, results of operations and cash flows. If the cost of our liability insurance increases significantly, or if this insurance becomes unavailable, we may not be able to maintain or increase our levels of insurance coverage for our directors and officers, which could make it difficult to attract or retain qualified directors and officers.

**If we fail to continue to meet all applicable NASDAQ Market requirements and NASDAQ determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.**

Our common stock is listed on the NASDAQ Capital Market (formerly known as the NASDAQ SmallCap Market). In order to maintain our listing, we must meet minimum financial and other requirements. If we are unable to comply with NASDAQ's listing standards, we may determine to delist our common stock from the NASDAQ Capital Market. On December 21, 2005, we received notice from NASDAQ stating that we were out of compliance with bid price requirements because the closing bid price for our common stock was below \$1.00 per share for 30 consecutive business days. On March 8, 2006 we received a letter from NASDAQ that we had regained compliance with the \$1.00 per share minimum bid price requirement for continued listing on the NASDAQ Capital Market. If in the future we do not meet the NASDAQ listing requirements based on minimum bid price for our common stock, we would have 180 days to regain compliance with bid price requirements. To regain compliance the closing bid price for our common stock must be a minimum of \$1.00 per share for at least 10 consecutive business days. If NASDAQ made a determination to delist our common stock, the delisting procedure would involve a process beginning with NASDAQ's notification and would include a hearing and the possibility of appeal. There is no

assurance that at the end of this process our common stock would continue to be listed on the NASDAQ Capital Market. If our common stock is delisted for any reason, it could reduce the value of our common stock and its liquidity. Delisting could also adversely affect our ability to obtain financing for the continuation of our operations or to use our common stock in acquisitions. Delisting could result in the loss of confidence by suppliers, customers and employees.

**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 and conducting our research and clinical programs, recruiting outside directors, employees and key consultants, evaluating potential compounds for in-licensing, 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, 2005, we had an accumulated deficit of \$91,122,000 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, 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 in-license compounds and develop potential drug products.**

We cannot assure you that our efforts will lead to the successful identification and in-licensing of potential compounds, or if so licensed, that our efforts 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, 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 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, which is being terminated. See Item 1, Business, Out-Licensed Technology, Section D. 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 license to CURE from the United States Public Health Service on behalf of the National Institute of Aging), our license to the patent rights covering certain 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. 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 this, 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.

We anticipate undertaking similar payment, development milestone, patent prosecution costs, and termination obligations under applications currently pending with NIH for certain patent rights to Posiphen and BNC, if such licenses are granted. Our business and prospects could be adversely affected if either or both of these licenses are not granted.

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.

**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, our potential butyrylcholinesterase inhibitor drug candidate, and Posiphen, a potential pharmaceutical compound for the treatment of AD that is the positive isomer of Phenserine. Because we are not the sole owner of the patent rights, future commercialization of Posiphen or Bisnorcymserine may be adversely impacted by the patent rights held by a third party with whom we do not currently have licensing agreements. We are currently seeking licenses from the third party 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 Bisnorcymserine or Posiphen. A decision not to commercialize these drug candidates could adversely affect our business.

**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 outside manufacturers to develop and manufacture drug product for our drug products.**

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, pre-clinical and clinical 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.

**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 pre-clinical testing and 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 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, S. Colin Neill, our Chief Financial Officer and Treasurer, and/or Paul Feuerman, our General Counsel, 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 us, 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.**

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 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 sub-licensees develop products based upon the licensed technology, and we have certain license applications pending with NIH. 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 are obligated to pay the filing, prosecution and maintenance expenses with regard to patents and patent applications we own or have licensed. We and our licensors have filed patent applications in other countries, and we may seek additional patents in the future. We cannot assure you as to the breadth or 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 or that we will be granted licenses to certain patents under our pending license applications. 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. Patent applications are often first published eighteen months or more after filing and the claim scope frequently undergoes substantial change between publication and issuance of a patent. Therefore, until a patent is issued, we may not be able to determine 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 parties 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 and CURE LLC, 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. 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. 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.

**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 our investment in OXIS International may face future impairment.**

Effective March 1, 2005, we accounted for our investment in OXIS under the equity method of accounting following accounting principles bulletin (APB) No. 18. Any impairment charge would be required if we determined that any reduction in the OXIS market value over the carry value was permanent.

#### **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 AD 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 AD 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 larger 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 AD area. Our major competitors are currently the pharmaceutical companies that are marketing the acetylcholinesterase inhibitors for the treatment of AD. The market for such is dominated primarily by Pfizer with its drug Aricept. 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 was approved in early 2004 as a 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. There can be no guarantees that we will be able to successfully find a partner to further develop Phenserine 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 majority of 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. One of our drug product candidates is currently in pre-clinical development, and two are in 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:

- finer,
- 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 (NICE) 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 sufficiently beneficial. 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 AD. 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:

| <b>Trademark Name</b> | <b>US Patent</b> | <b>Present Patent Expiration date</b> |
|-----------------------|------------------|---------------------------------------|
| Aricept               | 4,895,841        | Nov. 25, 2010                         |
| Reminyl               | 4,663,318        | Dec. 14, 2008                         |
| Exelon                | 4,948,807        | Aug. 14, 2007                         |

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. Currently at least Watson Pharmaceuticals and Ranbaxy, Inc. have obtained tentative approval from the FDA to market a generic version of rivastigmine. The owner of U.S. Patent 4,948,807 is in the early stages of enforcing its patent rights against the generic manufacturers.

**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 Capital 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 \$0.99. 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 been filed against us, has often been instituted against those companies. Please see Item 3, Legal Proceedings, and the risk factor above entitled `We are a defendant in a class action lawsuit and a shareholder derivative lawsuit.`

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, 2006, we had outstanding options to purchase an aggregate of 5,320,619 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 2,689,000 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 7,107,116 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 through a new offering of securities on terms more favorable than those provided by these warrants and options.

#### **Item 1B. Unresolved Staff Comments**

On November 23, 2005, we received a comment letter from the Staff of the SEC's Division of Corporate Finance with respect to our Form 10-K for the fiscal year ended December 31, 2004. We responded to the Staff's comments on December 6, 2005, received follow-up comments on the 2004 10-K from the Staff on January 16, 2006, and replied to such follow-up comments on January 27, 2006. On March 9, 2006, we received a second follow-up comment letter from the Staff with respect to our 2004 10-K. The remaining unresolved Staff comment asks us to clarify why our approach of consolidating OXIS as of December 31, 2004 and through February 28, 2005, was appropriate, or, alternatively, asks us to restate our 2004 financial statements to de-consolidate OXIS as of December 31, 2004. We believe that our approach of consolidating OXIS was appropriate and that a restatement is not necessary, and we are working with the Staff to clarify our position.

#### **Item 2. Properties**

During 2005, our operations were conducted from our offices in New York, New York, Stevenson, Washington and Salt Lake City, Utah. We lease approximately 1,014 square feet of office space in New York on a three month renewable basis at a rental rate of \$12,400 per month. We lease approximately 300 square feet of office space in Salt Lake City, Utah, on a month to month basis at \$1,100 per month for patent counsel.

Axonyx Europe BV, a wholly owned subsidiary of Axonyx Inc., rents approximately 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**

Several lawsuits were filed against us in February 2005 in the U.S. District Court for the Southern District of New York asserting 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). Dr. M. Hausman (a director and former CEO of Axonyx), Dr. G. Bruinsma (Axonyx CEO) and Mr. S. Colin Neill (Axonyx CFO) were also named as defendants in the lawsuits. These actions were consolidated into a single class action lawsuit in January 2006. It is anticipated that Plaintiff will file an amended consolidated complaint on or before March 27, 2006.

The class action plaintiffs 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 AD, which they allege had the effect of artificially inflating the price of our shares.

There is also a shareholder derivative suit pending in New York Supreme Court (New York County) against current and former directors and officers of Axonyx. The named defendants are Marvin S. Hausman, Gosse B. Bruinsma, S. Colin Neill, Louis G. Cornacchia, Steven H. Ferris, Gerald J. Vlak, Ralph Synderman and Michael A. Griffith. Defendants are alleged to have breached their duties to us and misused inside information regarding clinical trials of Phenserine. This action has been stayed pending further developments in the federal class action.

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 these actions, and, if the outcome is unfavorable to Axonyx, our reputation, operations and share price could be adversely affected.

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

We did not submit any matters to a vote our stockholders in the fourth quarter of 2005.

**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 Capital 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, 2004 and February 28, 2006. These quotations reflect prices between dealers, do not include retail mark-ups, mark-downs, and commissions and may not necessarily represent actual transactions.

| Period                                     | High    | Low     |
|--|---------|---------|
| <b>2004</b>                                |         |         |
| 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 |
| <b>2005</b>                                |         |         |
| Quarter ended 3/31/05                      | \$ 6.25 | \$ 1.14 |
| Quarter ended 6/30/05                      | \$ 1.63 | \$ 1.10 |
| Quarter ended 9/30/05                      | \$ 1.57 | \$ 0.99 |
| Quarter ended 12/31/05                     | \$ 1.18 | \$ 0.79 |
| <b>2006</b>                                |         |         |
| Period beginning 1/1/06 and ending 2/28/06 | \$ 1.20 | \$ 0.83 |

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

As of March 8, 2006 there were approximately 352 holders of record of our common stock, of which 53,680,721 shares were issued and outstanding.

We have never paid cash dividends on our 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, requirements, expansion plans, financial condition and other relevant factors.

**Item 6. Selected Financial Data**

**Years Ended December 31,**  
**(Dollars in thousands, except per share data)**

|   | 2005     | 2004     | 2003     | 2002    | 2001    |
|---|----------|----------|----------|---------|---------|
| <b>Statement of Operations Data:</b>                  |          |          |          |         |         |
| Total Revenues  | \$ 403   | \$ 2,275 | \$ 1,000 | \$ 0    | \$ 0    |
| Research and development expenses                     | 24,621   | 23,741   | 5,821    | 3,852   | 5,153   |
| General and administrative expenses                   | 5,143    | 8,250    | 3,459    | 2,505   | 3,277   |
| Loss from operations                                  | (29,571) | (30,883) | (8,280)  | (6,357) | (8,430) |
| Net Loss  | (28,614) | (28,780) | (8,106)  | (6,256) | (8,144) |
| Net Loss per share                                    | (.53)    | (.58)    | (.30)    | (.36)   | (.53)   |
| Weighted average shares outstanding<br>(in thousands) | 53,668   | 49,977   | 27,207   | 17,265  | 15,423  |

32

**Years Ended December 31,  
(Dollars in thousands)**

|  | 2005      | 2004      | 2003      | 2002     | 2001     |
|--|-----------|-----------|-----------|----------|----------|
| <b>Balance Sheet Data:</b>             |           |           |           |          |          |
| Cash, cash equivalents and investments | \$ 58,338 | \$ 90,591 | \$ 28,780 | \$ 4,474 | \$ 9,115 |
| Total assets                           | 64,042    | 101,394   | 28,815    | 7,984    | 9,211    |
| Accumulated deficit                    | (91,122)  | (62,508)  | (33,728)  | (25,622) | (19,366) |
| Total stockholders equity              | 58,383    | 86,538    | 26,651    | 6,649    | 8,191    |

**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-26 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 AD 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.

We currently have three compounds in development for AD: Phenserine, a potential symptomatic and disease progression treatment for mild to moderate AD; Posiphen, a potential disease progression treatment for AD, and Bisnorcymserine (BNC), a potential symptomatic treatment for severe AD.

**Phenserine**

To date, we have conducted the following Phase III clinical trials with Phenserine: AX-CL-06/06e, AX-CL-09, AX-CL-010 and AX-CL-06a (Phase IIb trial).

Protocol AX-CL-06 was a double-blind, placebo controlled trial initiated in June 2003 comparing the efficacy and tolerability of Phenserine 10mg or 15mg twice daily doses with twice daily placebo in patients who met diagnostic criteria for probable AD. Two different regimens, 10mg twice daily and 15mg twice daily, were compared with placebo in this trial. The randomization was 1:2:2 for placebo: 10mg twice daily:15mg twice daily. Patients randomized to active treatment were started on a 5mg twice daily regimen for the first month of treatment. This was increased to 10mg twice daily for the second month of treatment. The dose was increased to 15mg twice daily during the third month for patients randomized to the highest dose regimen. Once a patient reached his or her target dose, it was maintained for the duration of the trial for a total of 26 weeks. Patients who could not tolerate their target doses were discontinued. Discontinued patients were not replaced. A total of 384 patients were enrolled in the study. Of these, 377 received treatment. The remaining 7 never received drug treatment so were excluded from the data analyses.

The primary efficacy variables were the ADAS-Cog and CIBIC+. The Phenserine groups showed consistently greater improvement in ADAS-Cog and CIBIC+ scores than the placebo group although the differences did not achieve statistical significance.

Protocol 06A was a double-blind placebo controlled study of the effect of Phenserine 10 or 15mg twice daily on cerebrospinal and plasma peptides from baseline and at 26 weeks, initiated in June 2003. Although both doses of Phenserine tended to lower beta amyloid peptides more than placebo, none of the differences achieved statistical significance.

Protocol AX-CL-06e was an open-label extension to studies AX-CL-06 and AX-CL-06a to gather additional safety data on Phenserine treatment.

Protocol AX-CL-09/010, initiated in the second half of 2004, was originally initiated as two identical 26-week placebo controlled trials of 450 AD patients each. During the implementation of the studies, results of Protocol AX-CL-06 became available. The results of this earlier study showed a numerical benefit of Phenserine treatment relative to placebo but failed to achieve statistical significance. Based on these results, enrollment in the two ongoing studies was halted at 255 patients in total, and the duration of treatment was shortened to 12 weeks. Because the individual curtailed studies were underpowered, their data were combined and analyzed as a single trial. This was a randomized, multinational, multicenter placebo-controlled parallel-group study. Because the study was curtailed, many patients did not reach the originally scheduled 26-week end of treatment. However, all patients were allowed to complete at least 12 weeks of therapy. Patients were screened within 21 days of entry and randomly assigned to receive 10 or 15 mg of Phenserine twice daily or placebo. A titration schedule was used so that patients randomized to active treatment received 5mg twice daily for the first 4 weeks of the study followed by 10mg twice daily for 4 weeks. Patients randomized to 15 mg twice daily received this dose starting in the ninth week. Treatment at the assigned doses was continued for up to 26 weeks. At the 12-week visit, patients randomized to 10mg twice daily had received this dose for approximately 8 weeks. Patients randomized to receive 15mg twice daily had received this dose for approximately 4 weeks.

Although the study did not achieve statistical significance in its primary endpoints, patients treated with 15mg twice-daily Phenserine for greater than 12 weeks showed significant clinical benefit on the cognitive effects of AD.

Based on the analysis, we have determined not to commit further resources to the development of Phenserine given our financial resources. Positive signals were observed in all the trials to date, including the interim analyses of the Phase IIB beta amyloid trial. However, none of these trials achieved statistical significance for the primary end points. Therefore, we have decided to accelerate our marketing package for the out-licensing of Phenserine. The trials to date on Phenserine, including extensive preclinical studies, have provided us with a comprehensive set of data. Utilizing this data we will explore opportunities for out-licensing Phenserine to a company willing to commit the financial resources necessary to undertake further clinical trials. We will not incur any additional development expenses for Phenserine beyond those expenses needed to close the ongoing activities in an orderly fashion.

### **Posiphen**

In January 2006, we announced the completion of a single ascending dose Phase I trial with Posiphen, in clinical development for the treatment of AD progression. This double-blind, placebo controlled study of Posiphen in healthy men and women sought to establish well tolerated doses. Posiphen appears to be well tolerated at single doses up to and including 80mg. Blood levels of Posiphen associated with this study were higher than those associated with beneficial effects on beta-amyloid metabolism in animal models. The build-up of beta-amyloid (Ab) is generally believed to be causative of the dementia of AD. No serious adverse events were reported at any dose level.

### **Bisnorcymserine (BNC)**

Bisnorcymserine (BNC) is a highly selective butyrylcholinesterase inhibitor. Butyrylcholinesterase is found in high concentration in the plaques taken from individuals who have died from AD. Butyrylcholinesterase appears to have an increasing role with advancing AD and its primary mechanism of action results in a dose

dependent reduction of acetylcholine. The initial pre-clinical side effect rate potentially allows higher clinical doses. A secondary mechanism of action is associated with dose dependent reductions of beta APP and amyloid beta. BNC, the lead compound from our butyrylcholinesterase family, is currently in full pre-IND development and an IND submission is planned for second quarter of 2006, followed by the potential to initiate Phase I clinical trials thereafter.

#### **Other Pertinent Information**

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. This license is being terminated and we are negotiating reacquisition of the licensed rights. We cannot assure you that additional revenues from any other patent licensing activities will be generated.

Our current plan of operation for the next 12 months primarily involves research and development activities, including clinical trials for Posiphen and Bisnorcymserine. Our strategy for Phenserine is to seek licensing partners for further development.

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, 2005 Compared with the Year ended December 31, 2004**

For the year ended December 31, 2005, we had revenue of \$403,000 compared to \$2,275,000 for the year ended December 31, 2004. Revenues in 2005 and 2004 were derived from the sale of research assays and fine chemicals at OXIS and in 2004, a licensing agreement at OXIS for \$450,000. The reduction in revenue for the year ended December 31, 2005 from prior year levels results from the fact that OXIS operations are no longer being consolidated with our results effective March 1, 2005 as discussed in Note B[1] to the condensed consolidated financial statements.

Our costs of sales were entirely related to OXIS and the sale of its research assays and fine chemicals. The percentages of cost of sales for the years ended December 31, 2005 and 2004 were 52% and 64%, respectively.

For the year ended December 31, 2005, we incurred a net loss of \$28,614,000 compared to net loss of \$28,780,000 for the year December 31, 2004.

For the year ended December 31, 2005, we incurred research and development costs of \$24,621,000 compared to \$23,741,000 for the year ended December 31, 2004.

In 2005, research and development expenses increased \$880,000 or 3.7% over 2004 expenses. The increase reflects expenditures incurred in the Posiphen program of \$2,001,000 and the Bisnorcymserine (BNC) program of \$862,000 over prior year levels. During 2005, Posiphen entered clinical Phase I studies and Bisnorcymserine was in full pre-clinical development towards filing an investigational new drug application (IND). The Posiphen and BNC increased development costs in 2005 are offset in part by a decrease in the Phenserine program of \$1,215,000 over prior year levels due to the completion of Phenserine trials in late 2005. Our strategy with Phenserine is now to seek a licensing partner. Additional expense reductions compared to 2004 occurred from a decrease in non-cash charges for stock option grants to consultants of \$476,000, a decrease in other research and development expenses and a reduction in the amount of general and administrative expenses allocated to research and development. The total general and administrative expenses allocated to research and development in 2005 was \$715,000 compared to \$988,000 in 2004. Further, no bonuses were awarded in 2005.

OXIS accounted for \$41,000 and \$218,000 of research and development expenses in 2005 and 2004, respectively.

## Edgar Filing: AXONYX INC - Form 10-K

For the year ended December 31, 2005, we incurred general and administrative costs of \$5,143,000 compared to \$8,250,000 for the year ended December 31, 2004. The decrease of \$3,107,000 for 2005 was due to a decrease of \$2,193,000 in expenses from OXIS operations which are no longer consolidated with our results effective March 1, 2005 as discussed in Note B[1] to the condensed consolidated financial statements, and a decrease of \$1,930,000 in non-cash charges relating to stock option grants to consultants. These declines are offset in part by an increase in professional fees of \$1,105,000. The increase in professional fees is primarily attributed to utilization of additional outside counsel, patent filing costs, legal costs related to class action securities litigation, Sarbanes Oxley compliance and board member fees. A decrease of \$287,000 in 2005 in filing fees, investor relations costs, travel expenses, subsidiary management costs and other operating expenses is offset in part by a \$256,000 increase in insurance costs due to expanded insurance coverage.

General and administrative salaries decreased by a net of \$205,000 in 2005 over 2004. We have entered into a consulting agreement with the former CEO and Chairman effective September 2005, thus reducing payroll costs. In addition, no bonuses were awarded in 2005. During 2005, we added both General Counsel and Patent Counsel to payroll.

Interest income for the year ended December 31, 2005 was \$2,235,000 compared to \$1,235,000 for the year ended December 31, 2004. The increase in interest income is attributable to increases in short-term interest rates in 2005.

For the year ended December 31, 2005, the loss on foreign exchange was \$109,000 compared to a loss of \$83,000 on foreign exchange for the year ended December 31, 2004. The loss resulted from Euro purchased and utilized to meet vendor payments denominated in Euro.

In 2005, we recognized a loss of \$314,000 on issuance of common stock by OXIS. A loss of \$398,000 results from a correction that was required in the calculation of the gain on subsidiary stock under SEC Staff Accounting Bulletin No. 51. The gain resulted from the issuance of shares by OXIS at December 31, 2004 in connection with a private placement financing. The correction has been effected by a \$398,000 reduction in the carrying value of the investment in OXIS at March 31, 2005 with a corresponding reduction in the loss on issuance of subsidiary stock for the period then ended in accordance with the provisions of Accounting Principles Board Opinion No. 28, Interim Financial Reporting as it is not material to either the 2004 or 2005 results of operations or to the trend of operations.

As of March 1, 2005, we account for our investment in OXIS under the equity method of accounting. The equity in the loss of OXIS reflects our 34% share of the 2005 loss reported by OXIS for the period March 1, 2005 to December 31, 2005. On December 6, 2005 OXIS acquired a 51% interest in BioCheck Inc. and as a result of that transaction, OXIS expensed in-process research and development costs aggregating \$1,500,000, of which 34% or \$510,000 is included in the equity of loss of OXIS of \$1,017,000.

In 2004, we 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.

We incur expenses in Euro currency for Phenserine clinical trials that were conducted in Europe. Additionally, our European subsidiary in the Netherlands is funded from the U.S.

### **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 AD.

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

## Edgar Filing: AXONYX INC - Form 10-K

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 was subsequently 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 had 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, we 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.

We incur expenses in Euro currency, as currently the Phenserine clinical trials are being conducted in Europe. Additionally, our European office in the Netherlands is funded from the U.S.



**C. Liquidity and Capital Resources**

As of December 31, 2005, we had \$1,638,000 in cash and cash equivalents, \$56,700,000 in investments and \$53,293,000 in working capital.

Net cash used in operating activities for the year ended December 31, 2005 was \$29,588,000 resulting from a net loss of \$28,614,000, a decline in accounts payable and accrued expenses of \$1,937,000, a decline in accrued stock based compensation of \$386,000 and an increase in other current assets of \$581,000. These declines are offset in part by \$549,000 in depreciation and amortization, \$425,000 of option and warrant compensation, a loss on issuance of subsidiary stock of \$314,000 and \$1,017,000 in equity in loss of OXIS.

Net cash provided by investing activities for the year ended December 31, 2005 was \$18,832,000, resulting principally from investment sales and maturities in excess of investment purchases, and the deconsolidation of OXIS of \$4,907,000.

Net cash from financing activities for the year ended December 31, 2005 was \$2,303,000. In January 2005, OXIS received \$2,250,000 of stock subscription receivable from a December 31, 2004 private placement.

We currently have contracts with JSW Research of Austria and PPD Global Ltd. relating to the 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.

| Vendor                                | Total<br>Contract(s) | Paid<br>Through<br>December<br>31, 2005 | Total<br>Remaining<br>Contract<br>Liability | 2006                |
|---------------------------------------|----------------------|---|---|---------------------|
| Ace Pharmaceutical                    | 212,520              | 133,488                                 | 79,032                                      | 79,032              |
| Avtech Laboratories                   | 304,782              | 121,828                                 | 182,954                                     | 182,954             |
| Biodynamics                           | 105,000              | 30,000                                  | 75,000                                      | 75,000              |
| Bioreliance                           | 60,400               | 36,240                                  | 24,160                                      | 24,160              |
| BioStat                               | 102,390              | 39,555                                  | 62,835                                      | 62,835              |
| Charles River Labs                    | 156,200              |   | 156,200                                     | 156,200             |
| Covance Laboratories                  | 89,000               | 74,400                                  | 14,600                                      | 14,600              |
| DataMagik                             | 1,109,401            | 607,140                                 | 502,261                                     | 502,261             |
| Eurochem                              | 14,080               |   | 14,080                                      | 14,080              |
| Indiana University School of Medicine | 175,753              | 87,876                                  | 87,877                                      | 87,877              |
| JSW Research                          | 8,047,274            | 7,047,653                               | 999,621                                     | 999,621             |
| Kendle                                | 443,812              | 438,238                                 | 5,574                                       | 5,574               |
| Karolinska University                 | 1,952,509            | 1,637,531                               | 314,978                                     | 314,978             |
| MDSPS                                 | 161,800              |   | 161,800                                     | 161,800             |
| Medical University of South Carolina  | 411,940              | 336,143                                 | 75,797                                      | 75,797              |
| Patheon                               | 213,445              | 142,945                                 | 70,500                                      | 70,500              |
| PPD Global                            | 12,013,555           | 10,880,146                              | 1,133,409                                   | 1,133,409           |
| PRACS                                 | 257,400              | 102,960                                 | 154,440                                     | 154,440             |
| PSPG                                  | 2,665,920            | 2,332,680                               | 333,240                                     | 333,240             |
| Rhodia                                | 182,000              | 72,800                                  | 109,200                                     | 109,200             |
| Synkem                                | 84,600               |   | 84,600                                      | 84,600              |
| Wil Research Labs                     | 376,300              | 361,080                                 | 15,220                                      | 15,220              |
| Xenotech                              | 50,606               | 45,545                                  | 5,061                                       | 5,061               |
| <b>Total</b>                          | <b>\$ 29,190,687</b> | <b>\$ 24,528,248</b>                    | <b>\$ 4,662,439</b>                         | <b>\$ 4,662,439</b> |

We plan to finance our needs principally from the following:

our existing resources and interest earned on that ;

through future private placement financing or other equity financings.

We believe that we have sufficient resources to finance our plan of operation at least through March 31, 2007. 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 our drug development programs, 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, 2007, 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 had less than a majority ownership at December 31, 2004, the accounts of OXIS were consolidated as the Company controlled the board of directors through a majority of the OXIS board seats, which enabled it to effectively control significant decisions made in the ordinary course of business. 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 had a majority of the seats on the OXIS Board, and because the Company's ownership interest was 34% of the OXIS shares outstanding, beginning March 1, 2005 OXIS was no longer 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:** 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.

**Accounting for stock sales by subsidiary:** We account 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 our consolidated financials. These gains amounted to \$1,154,000 relating to OXIS in 2004, arising primarily from its December 2004 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 May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections - A Replacement Of APB Opinion No. 20 AND FASB Statement No. 3 (SFAS 154). SFAS 154 requires retrospective application to prior periods financial statements for changes in accounting principle. SFAS 154 also requires that a change in depreciation, amortization, or depletion method for long-lived, non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The implementation of SFAS 154 is not expected to have a material impact on our results of operations, financial position or cash flows.

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 supersedes 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. The impact of adopting SFAS 123R cannot be currently estimated since it will depend on share based payments granted in the future. However, had the Company adopted SFAS 123R in prior periods, the impact would have approximated the impact of SFAS 123 as described in the disclosure of proforma net loss and net loss per share in Note 11 to the company's consolidated financial statements included elsewhere herein.

#### **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, 2005 of \$109,000. If the foreign currency rates were to fluctuate by 10% from rates at December 31, 2005 and 2004, 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 and time deposits as cash and cash equivalents. The carrying values of these investments approximate fair value because of these instruments and accounts. We

classify our investments in auction rate securities as short-term investments. The carrying value of these securities approximates fair value because of the liquidity they are traded as short term investments due to the interest reset feature. 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-26 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**

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has reviewed and evaluated the effectiveness of the Company's disclosure controls and procedures as of December 31, 2005. Disclosure controls and procedures are defined in the Securities Exchange Act as controls and other procedures of the Company designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and include controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits to the SEC is accumulated and communicated to the Company's management, including the CEO and CFO, to allow timely decisions regarding required disclosure. Based on its review and evaluation, the Company's management has concluded that the Company's disclosure controls and procedures were effective as of December 31, 2005.

**Management's Annual Report on Internal Control over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in the Securities Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers, or persons performing similar functions, and effected by the Company's board of directors, management and other personnel, 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. Internal control over financial reporting includes those policies and procedures that pertain to the maintenance of records that in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company, 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 the Company's management and directors and 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.

The Company's management, under the supervision and with the participation of the Company's CEO and CFO, carried out an assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2005. The Company's management based its evaluation on criteria set forth in the framework in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2005.

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

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
Axonyx Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that AXONYX Inc. (the Company) maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company'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 accounting principles generally accepted in the United States of America. 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 accounting principles generally accepted in the United States of America, 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, 2005, is fairly stated, in all material respects, based on criteria established in Internal Control - Integrated Framework issued by COSO. Also, in our opinion, Axonyx maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control - Integrated Framework issued by COSO.

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, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2005, and our report dated January 30, 2006 expressed an unqualified opinion on those consolidated financial statements.

Eisner LLP  
New York, New York  
January 30, 2006

**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>  |
|-------------------------|------------|--|
| Gosse B. Bruinsma, M.D. | 51         | President & Chief Executive Officer<br>President of Axonyx Europe BV, Director |
| S. Colin Neill          | 59         | Chief Financial Officer, Treasurer & Secretary                                 |
| Paul M. Feuerman        | 46         | General Counsel  |
| Steven B. Ratoff        | 63         | Chairman of the Board, Director  |
| Marvin S. Hausman, M.D. | 64         | Director   |
| Steven H. Ferris, Ph.D. | 62         | Director   |
| Louis G. Cornacchia     | 72         | Director   |
| Ralph Snyderman, M.D.   | 66         | 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.** Dr. Hausman has been a director of Axonyx since its founding in 1996. He served as President from 1997 until 2003 (when Dr. Bruinsma was appointed President) and as Chief Executive Officer from 1997 until 2005 (when Dr. Bruinsma was appointed Chief Executive Officer). Dr. Hausman served as Chairman of the Board of Directors from 2003 until September 2005. 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.** Dr. 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. He joined the Axonyx board in 2001. Since September 2003, Dr. Bruinsma also has served as President of the Company. On March 3, 2005, we announced that Dr. Bruinsma became the CEO of our company. 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, 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.

**Steven B. Ratoff** Mr. Ratoff joined the Axonyx Board of Directors in May 2005. In September 2005, Mr. Ratoff became Chairman of the Board. Mr. Ratoff is currently a private investor and a Venture Partner with Proquest Investments, a biopharmaceutical venture firm. He most recently served as Chairman and Interim Chief Executive Officer of Cima Labs, Inc., a public specialty pharmaceutical company, from May 2003 through its sale to Cephalon, Inc. in August 2004. He was the President and Chief Executive Officer of MacroMed, Inc., a privately owned drug delivery company, from February 2001 to December 2001, and also as director since 1998. Mr. Ratoff's experience includes serving as Executive Vice President and Chief Financial Officer of Brown-Forman Corporation, a public diversified manufacturer of consumer products, as well as fifteen years in a variety of senior financial positions with Bristol-Myers Squibb. Mr. Ratoff is currently a director of Novadel Pharma Inc.

**Paul Feuerman** Mr. Feuerman joined Axonyx Inc. in June 2005 as General Counsel. Mr. Feuerman is a founding member of PharmAdvisors LLC, a consulting firm serving pharmaceutical and biopharmaceutical companies. Formerly, he was Executive Vice President and General Counsel of Schein Pharmaceutical Inc., a New York Stock Exchange listed specialty pharma/generics company. Previously, Mr. Feuerman was associated with the law firm of Proskauer Rose LLP. He received his BA from Trinity College and his JD from Columbia Law School.

**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 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 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 2003. Louis Cornacchia has extensive experience in managing several engineering consultancy companies. Louis Cornacchia received a bachelor's degree 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 2003. Dr. Ferris is a neuropsychologist, psychopharmacologist, and gerontologist who has been studying brain aging and AD 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 AD. 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 AD. 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 AD.

**Ralph Snyderman, M.D.** Dr. Ralph Snyderman has served as director of Axonyx since March 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.

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. The Corporate Governance Principles will be made available shortly in the Investors section of the Company's website at [www.axonyx.com](http://www.axonyx.com).

We have constituted Audit, Nominating/Governance and Compensation Committees. The Audit Committee consists of Messrs. Steven Ratoff, Steven Ferris, and Louis Cornacchia who are all outside directors. The Nominating/Governance Committee consists of Steven Ratoff, Steven Ferris, and Ralph Snyderman and the Compensation Committee consists of Steven Ratoff, Louis Cornacchia, and Ralph Snyderman.

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: Steven Ratoff 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 available in the Investors section of the Company's website at [www.axonyx.com](http://www.axonyx.com). Click Investors and then Corporate Governance.

As part of our system of corporate governance, our Board of Directors in November 2005 adopted a revised Code of Business Conduct and Ethics that is applicable to all employees and specifically applicable to our chief executive officer and 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, 10<sup>th</sup> Floor, New York, NY 10018, (Tel.) 212-645-7704. The Code of Business Conduct and Ethics is available in the Investors section of the Company's website at [www.axonyx.com](http://www.axonyx.com). Click Investors and then Corporate Governance. 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.

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

No person who, during the fiscal year ended December 31, 2005, was a director, officer or beneficial owner of more than ten percent of our Common Stock which is the only class of securities we 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 us with respect to its most recent fiscal year, and any representation received by us 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, 2003, December 31, 2004 and December 31, 2005 to our Chief Executive Officer and each of the highest paid of our executive officers whose annual salary and bonus for fiscal year 2005 exceeded \$100,000 (collectively, the Named Executive Officers).

**Annual Compensation (3)**

| <b>Name and<br/>Principal<br/>Occupation</b> | <b>Year</b> | <b>Salary<br/>(\$)</b> | <b>Bonus<br/>(\$)</b> | <b>Other<br/>(\$)</b> | <b>Long term<br/>Compensation<br/>Awards<br/>Securities<br/>underlying<br/>Options (#)</b> |
|--|-------------|------------------------|-----------------------|-----------------------|--|
| Marvin S. Hausman, Director (5)              | 2005        | \$ 335,042             | \$                    | \$ 114,151            |  |
|  | 2004        | \$ 394,375             | \$ 200,000            | \$ 54,376             | 200,000  |
|  | 2003        | \$ 250,000             | \$ 175,000            | \$ 31,719             | 325,000(4)   |
| Gosse B. Bruinsma, President and CEO<br>(1)  | 2005        | \$ 412,500             | \$                    | \$ 31,250             | 200,000  |
|  | 2004        | \$ 372,000             | \$ 150,000            | \$ 31,000             | 100,000  |
|  | 2003        | \$ 253,000             | \$ 100,000            | \$ 28,250             | 300,000(4)   |
| S. Colin Neill, CFO, Sec. & Treasurer (2)    | 2005        | \$ 247,500             | \$                    | \$ 16,989             | 50,000   |
|  | 2004        | \$ 212,000             | \$ 100,000            | \$ 10,000             | 50,000   |
|  | 2003        | \$ 52,000              | \$ 10,000             | \$ 2,915              | 210,000(4)   |
| Paul M. Feuerman, General Counsel (6)        | 2005        | \$ 160,385             | \$                    | \$ 5,743              | 150,000  |

- (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. Dr. Bruinsma's salary for 2005 was Euro 330,000 and his expense allowance was Euro 25,000. These amounts are reflected in the table above at the average dollar/euro exchange rate of 1.25 for 2005, 1.24 for 2004, and 1.13 for 2003. Dr. Bruinsma succeeded Dr. Hausman as 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 and a \$6,989 employer 401k matching contribution.
- (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) We reimbursed the Chairman and CEO \$38,517 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. In September 2005 we entered into a one year consulting agreement with Dr. Hausman at the rate of \$20,000 per month through September 15, 2006. \$70,000 was paid under this agreement in 2005. Dr. Hausman received a \$5,634 employer 401k matching contribution.
- (6) Paul Feuerman received a \$5,743 employer 401k matching contribution.

**B. Option Grants in Fiscal Year 2005**

The following table sets forth certain information with respect to option grants to our Named Executive Officers in 2005. 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 2005

| Name                  | Individual Grants                                   |  |                                | Expiration date | 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) |                 | 5% (\$)  | 10% (\$)   |
| Gosse B. Bruinsma (2) | 200,000   | 41.9%  | \$ 1.05                        | 10/17/15        | \$ 132,068   | \$ 334,686 |
| S. Colin Neill (3)    | 50,000  | 10.5%  | \$ 1.05                        | 10/17/15        | \$ 33,017  | \$ 83,671  |
| Paul M. Feuerman (4)  | 150,000   | 31.4%  | \$ 1.27                        | 9/11/15         | \$ 119,804   | \$ 303,608 |

- (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 our estimate of the future market price of the common stock.
- (2) On October 18, 2005, we granted 200,000 Incentive Stock Options exercisable at \$1.05 per share to Gosse B. Bruinsma, M.D., with 50,000 options vesting on October 18, 2005, 2006, 2007 and 2008.
- (3) On October 18, 2005, we granted 50,000 Incentive Stock Options exercisable at \$1.05 per share to S. Colin Neill, with 12,500 options vesting on October 18, 2005, 2006, 2007 and 2008.
- (4) On September 12, 2005, we granted 150,000 Incentive Stock Options exercisable at \$1.27 per share to Paul M. Feuerman, with 37,500 options vesting on September 12, 2005, 2006, 2007 and 2008.

## C. Aggregate Option Exercises in Fiscal Year 2005 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, 2005.

## Aggregated Option Exercises in Fiscal Year 2005 and Year-End Option Values

| Name                  | Number of shares acquired on exercise | Value (\$)<br>Realized | Number of securities underlying unexercised options at fiscal year end | Value of unexercised in-the-money options at fiscal year end |
|-----------------------|---------------------------------------|------------------------|--|--|
|                       |                                       |                        |  | (1)  |
|                       |                                       |                        | Exercisable/<br>unexercisable  | Exercisable/<br>unexercisable                                |
| Marvin S. Hausman, MD |                                       |                        | 743,750/   | \$ 0/  |
| Director              |                                       |                        | 181,250  | \$ 0   |
| Gosse B. Bruinsma, MD |                                       |                        | 650,000/   | \$ 0/  |

Edgar Filing: AXONYX INC - Form 10-K

|                                   |          |    |    |
|-----------------------------------|----------|----|----|
| President<br>and CEO<br>(2)       | 275,000  | \$ | 0  |
| S. Colin<br>Neill                 | 195,000/ | \$ | 0/ |
| C h i e f<br>Financial<br>Officer | 115,000  | \$ | 0  |
| Paul M.<br>Feuerman               | 37,500/  | \$ | 0/ |
| G e n e r a l<br>Counsel          | 112,500  | \$ | 0  |

49

- (1) Dollar amounts reflect the net values of outstanding stock options computed as the difference between \$0.83 (the fair market value at December 31, 2005) and the exercise price of the options.
- (2) Dr. Bruinsma replaced Dr. Hausman as CEO effective March 3, 2005.

**D. Compensation to Directors**

In June of 2005, we adopted the following policy to compensate outside directors: The chairman of the audit committee 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 \$50,000 annually for their services on the board. In addition, we have agreed to reimburse our directors for reasonable expenses incurred in attending meetings of the board of directors and its committees. Individual directors may elect to receive stock options in lieu of their director or chairman fees.

Outside directors may be granted stock options on a discretionary basis. In 2005, Dr. Steven Ferris, and Mr. Louis Cornacchia received 50,000 stock options each. Dr. Ralph Snyderman received 56,912 stock options, and Mr. Steven Ratoff received 169,107 stock options.

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

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

Gosse B. Bruinsma, M.D., President, Chief Executive Officer and Director. On September 21, 2002 we 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. If the agreement is not renewed by the Company, Dr. Bruinsma is entitled to six months of severance.

In March 2004, following approval of the Compensation Committee and the Board, we entered into change of control agreements with Marvin S. Hausman, Gosse Bruinsma and S. Colin Neill, and in September 2005 with Paul Feuerman. Each agreement, as amended, 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 an amount equal to 30% (as to Messrs. Neill and Feuerman) and 40% (as to Dr. Bruinsma) of such executive's base salary. 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 our 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 our stockholders of a transaction where such change of voting control or composition of the Board would occur, where we would be liquidated or where all or substantially all of our 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 2005 were Dr. Steven Ferris, Mr. Michael A. Griffith (until his resignation from the board in April 2005), Mr. Steven B. Ratoff (since May 2005), Mr. Louis Cornacchia and Dr. Ralph Snyderman. None of the members of the Compensation Committee has ever been an officer or employee of ours or any subsidiary, nor have they had a relationship with us 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, 2006, 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, 2006 there were 53,680,721 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, 2006 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.

| Name of Beneficial Owner (1)                                | Number of<br>Shares<br>Beneficially<br>Owned | Percent of<br>Class |
|---|--|---------------------|
| Marvin S. Hausman, M.D. (2)                                 | 2,907,609                                    | 5.34%               |
| Gosse B. Bruinsma, M.D. (3)                                 | 700,500                                      | 1.29%               |
| S. Colin Neill (4)  | 195,000                                      | 0.36%               |
| Paul Feuerman (5)   | 37,500                                       | 0.07%               |
| Louis G. Cornacchia (6)                                     | 301,122                                      | 0.56%               |
| Steven H. Ferris, Ph.D. (7)                                 | 151,500                                      | 0.28%               |
| Steven Ratooff (8)  | 334,554                                      | 0.62%               |
| Ralph Snyderman, M.D. (9)                                   | 144,412                                      | 0.27%               |
| All directors and executive officers (8 persons) as a group | 4,772,197                                    | 8.53%               |
| Lloyd I. Miller LLC (10)                                    | 3,267,952                                    | 6.09%               |
| William S. Fagan (11)                                       | 6,734,630                                    | 12.55%              |
| Morgan Stanley & Co., Inc. (12)                             | 2,704,074                                    | 5.04%               |

- (1) Unless otherwise indicated, the address of each of the listed beneficial owners identified above is c/o 500 Seventh Avenue, 10<sup>th</sup> Floor, New York, NY 10018.
- (2) Marvin S. Hausman, M.D. Includes: (i) 2,113,859 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, (iv) 250,000 vested but unexercised options exercisable at \$3.16 per share granted on December 11, 2001, and (v) 93,750 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) 100,000 vested but unexercised options exercisable at \$7.03 per share granted on December 7, 2004, (vii) 50,000 vested but unexercised options exercisable at \$1.18 per share granted on March 17, 2003, and (viii) 50,000 unvested options exercisable at \$1.18 per share granted on March 17, 2003 that will vest within 60 days after February 28, 2006. 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 a non-affiliated donee in April 2003, (xvii) 1,000 shares gifted to Roberta Matta in April 2003, (xviii) 2,000 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) 1,000 shares gifted to Roberta Matta in December 2004, (xxiv) 1,000 shares gifted to four family members in December 2004, (xxv) 36,000 shares gifted to two non-affiliated donees in July 2005, (xxvi) 15,000 shares gifted to an adult child in July 2005 and (xxvii) 31,250 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) 100,000 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) 200,000 vested but unexercised options exercisable at \$3.16 per share granted on December 11, 2001; (v) 75,000 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) 50,000 vested but unexercised options exercisable at \$7.03 per share granted on December 7, 2004; (vii) 50,000 vested but unexercised options exercisable at \$1.07 per share granted on March 17, 2003, (viii) 25,000 vested but unexercised options exercisable at \$2.89 per share granted on June 11, 2002, (ix) 50,000 vested but unexercised options exercisable at \$1.05 per share granted on October 18, 2005 and (x) 50,000 unvested options exercisable at \$1.07 per share granted on March 17, 2003 that will vest within 60 days after February 28, 2006. Does not include (i) 25,000 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, (ii) 50,000 unvested options exercisable at \$7.03 per share granted December 7, 2004, and (iii) 150,000 unvested options exercisable at \$1.05 per share granted on October 18, 2005.
- (4) S. Colin Neill. Includes: (i) 150,000 vested but unexercised options exercisable at \$3.76 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) 7,500 vested but unexercised option exercisable at \$3.61 granted on November 18, 2003, (iii) 25,000 vested but unexercised options exercisable at \$7.03 per share granted December 7, 2004, and (iv) 12,500 vested but unexercised options exercisable at \$1.05 granted on October 18, 2005. Does not include: (i) 50,000 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) 2,500 unvested options exercisable at \$3.61 per share granted on November 18, 2003, (iii) 25,000 unvested options exercisable at \$7.03 per share granted December 7, 2004 and (iv) 37,500 unvested options exercisable at \$1.05 per share granted on October 18, 2005.
- (5) Paul Feuerman. Includes: (i) 37,500 vested but unexercised options exercisable at \$1.27 per share granted on September 12, 2005. Does not include (i) 112,500 unvested options exercisable at \$1.27 per share granted on September 12, 2005.
- (6) Louis G. Cornacchia. Includes: (i) 138,622 shares owned by Mr. Cornacchia; (ii) 40,000 vested but unexercised options exercisable at \$0.825 per share granted on February 21, 2003 (iii) 37,500 vested but unexercised options exercisable at \$4.24 per share granted September 23, 2003 (iv) 50,000 vested but unexercised options exercisable at \$5.27 per share granted October 12, 2004, (v) 25,000 vested but unexercisable options exercisable at \$1.22 granted on June 16, 2005 and (vi) 10,000 unvested options exercisable at \$0.825 per share granted on February 21, 2003 that will vest in the next sixty days after February 28, 2006. Does not include: (i) 12,500 unvested options exercisable at \$4.24 per share granted September 23, 2003, and (ii) 25,000 unvested options exercisable at \$1.22 per share granted on June 16, 2005.
- (7) 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 May 5, 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) 37,500 vested but unexercised options exercisable at \$4.24 per share granted September 23, 2003, (vi) 25,000 unvested options exercisable at \$1.22 per share granted on



June 16, 2005 and (vii) 50,000 vested but unexercised options exercisable at \$5.27 per share granted October 12, 2004. Does not include: (i) 12,500 unvested options exercisable at \$4.24 per share granted September 23, 2003, (ii) 25,000 unvested options exercisable at \$1.22 per share granted June 16, 2005 and (iii) 10,000 unvested options exercisable at \$1.11 per share granted January 14, 2003.

- (8) Steven Ratoff. Includes: (i) 250,000 shares owned by Steven Ratoff; (ii) 25,000 vested but unexercised options exercisable at \$1.18 per share granted on May 5, 2005; (iii) 25,000 vested but unexercised options exercisable at \$1.22 per share granted on June 16, 2005; (iv) 34,554 vested but unexercised options exercisable at \$1.21 per share granted on August 15, 2005. Does not include: (i) 25,000 unvested options exercisable at \$1.18 per share granted on May 5, 2005, (ii) 25,000 unvested options exercisable at \$1.22 per share granted on June 16, 2005 and (iii) 34,553 unvested options exercisable at \$1.21 per share granted on August 15, 2005.
- (9) Ralph Snyderman, M.D. Includes: (i) 25,000 vested but unexercised options exercised at \$7.09 per share granted on March 8, 2004, (ii) 50,000 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 after February 28, 2006, (iv) 25,000 vested but unexercised options exercisable at \$6.68 per share granted December 21, 2004, (v) 25,000 vested but unexercised options exercisable at \$1.22 granted on June 16, 2005, and (vi) 6,912 vested but unexercised options exercisable at \$1.21 per share granted on August 15, 2005. Does not include: (i) 12,500 unvested options exercisable at \$7.09 per share granted on March 8, 2004 (ii) 25,000 unvested options exercisable at \$1.22 per share granted June 16, 2005, and (ii) 25,000 unvested options exercisable at \$6.68 per share granted December 21, 2004.
- (10) Lloyd I. Miller, LLC, 4550 Gordon Drive, Naples, Florida, 34102. This information is based on a Schedule 13G filed by the holder on February 14, 2006 and is as of December 31, 2005.
- (11) William S. Fagan and affiliated parties, Fagan Capital, Inc., 5201 N. O Connor Blvd., Suite 440, Irving, Texas 75039. This information is based on a Schedule 13G filed by the holder on February 14, 2006 and is as of December 31, 2005.
- (12) Morgan Stanley & Co., Inc., 1585 Broadway, New York, New York 10036. This information is based on a Schedule 13G filed by the holder on February 15, 2006 and is as of December 31, 2005.

**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, 2005.

| Plan Category  | (a)<br>Number of securities<br>to be<br>issued upon exercise<br>of<br>outstanding options,<br>warrants<br>and rights. | (b)<br>Weighted-<br>average<br>exercise price of<br>outstanding<br>options,<br>warrants, and<br>rights | (c)<br>Number of securities<br>remaining<br>available for future issuance<br>under<br>equity compensation plans<br>(excluding<br>securities reflected in column<br>(a)) |
|--|---|--|---|
| Equity compensation plan approved by security holders (1)  | 944,100   | \$ 5.84  |   |
| Equity compensation plan approved by security holders (2)  | 4,134,000   | \$ 3.60  | 2,689,000   |
| Equity compensation plans not approved by security holders | 242,500(3)  | \$ 3.01  |   |
|  |   | \$ 3.98  |   |
| Total  | 5,320,600   |  | 2,689,000   |

- (1) As of February 28, 2006, we have granted options to purchase an aggregate of 944,100 shares of common stock under our 1998 Stock Option Plan. As of December 31, 2005, no options are available for future grant under the 1998 plan. The plan terminated on January 15, 2003.
- (2) As of February 28, 2006, we have granted options to purchase an aggregate of 4,134,019 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, we 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**

We have reimbursed the former Chairman and director for certain costs incurred in maintaining an office and related support in Portland, Oregon. The amounts in 2005 and 2004 were \$39,000 and \$54,000, 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 our consolidated financial statements as of and for the years ended December 31, 2005, and 2004, its reviews of our unaudited condensed consolidated interim financial statements, and for SEC consultations and filings were \$122,000 and \$153,000, respectively.

**AUDIT-RELATED FEES**

The audit-related fees billed for professional services rendered by Eisner LLP for the years ended December 31, 2005, and 2004 were \$93,500 and \$26,500, 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, 2005, and 2004 were \$10,000 and \$11,000, 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 2005 or 2004.

**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 us 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 2005.

**Item 15. Exhibits and Financial Statement Schedules**

**Consolidated Financial Statements:**

|  | <u>Page</u> |
|--|-------------|
| Report of Independent Registered Public Accounting Firm  | F-3         |
| Balance sheets as of December 31, 2005 and 2004  | F-4         |
| Statements of operations for each of the years in the three-year period ended December 31, 2005                      | F-5         |
| Statements of changes in stockholders' equity for each of the years in the three-year period ended December 31, 2005 | F-6         |
| Statements of cash flows for each of the years in the three-year period ended December 31, 2005                      | F-7         |
| Notes to consolidated financial statements   | F-8         |

**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))

## Edgar Filing: AXONYX INC - Form 10-K

- 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)
- 4.13 Rights Agreement, dated as of May 13, 2005, between Axonyx Inc. and The Nevada Agency and Trust Company, as Rights Agent (incorporated by reference to Exhibit 99.2 to the current report on Form 8-K previously filed by Axonyx Inc. on May 16, 2005)
- 4.14 Certificate of Designation of the Voting Powers, Designation, Preferences and Relative, Participating, Optional or Other Special Rights and Qualifications, Limitations and Restrictions of the Series A Preferred Stock (incorporated by reference to Exhibit A of the Rights Agreement filed as Exhibit 99.2 to the current report on Form 8-K previously filed by Axonyx Inc. on May 16, 2005)
- 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)

## Edgar Filing: AXONYX INC - Form 10-K

- 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 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))



## Edgar Filing: AXONYX INC - Form 10-K

- 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)
- 10.36\*\* Form of Change of Control Agreement between Axonyx Inc. and Paul Feuerman, dated as of September 12, 2005 (incorporated by reference to exhibit 99.1 to the registrant s Current Report on Form 8-K filed September 16, 2005).
- 10.37\*\* Form of Amendment to Change of Control Agreement between Axonyx Inc. and Gosse Bruinsma, S. Colin Neill and Paul Feuerman, dated as of November 30, 2005 (incorporated by reference to exhibit 99.1 to the registrant s Current Report on Form 8-K filed December 6, 2005).
- 10.38\*\* Consulting Agreement between Axonyx Inc. and Marvin S. Hausman, M.D., dated as of June 24, 2005 (incorporated by reference to exhibit 99.1 to the registrant s Current Report on Form 8-K filed June 30, 2005).
- 10.39\*\* Amendment to Consulting Agreement between Axonyx Inc. and Marvin S. Hausman, M.D., dated as of November 30, 2005 (incorporated by reference to exhibit 99.2 to the registrant s Current Report on Form 8-K filed December 6, 2005).
- 14 Code of Business Conduct and Ethics\*

Edgar Filing: AXONYX INC - Form 10-K

|      |  |
|------|--|
| 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 a management contract or compensatory plan or arrangement

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



**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly 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, 2006.

AXONYX INC.

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

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities indicated on this 16th day of March, 2006.

| <u>Signature</u>                     | <u>Title</u>   |
|--------------------------------------|--|
| /s/ Gosse B. Bruinsma, M.D.<br>_____ | President and Chief Executive Officer, (Principal Executive Officer),<br>Director                |
| Gosse B. Bruinsma, M.D.              |  |
| /s/ Steven B. Ratoff<br>_____        | Director and Chairman  |
| Steven B. Ratoff                     |  |
| /s/ S. Colin Neill<br>_____          | Chief Financial Officer, Treasurer and Secretary (Principal Financial<br>and Accounting Officer) |
| S. Colin Neill                       |  |
| /s/ Louis G. Cornacchia<br>_____     | Director   |
| Louis G. Cornacchia                  |  |
| /s/ Steven H. Ferris, Ph.D.<br>_____ | Director   |
| Steven H. Ferris, Ph.D.              |  |
| /s/ Marvin S. Hausman, M.D.<br>_____ | Director   |
| Marvin S. Hausman, M.D.              |  |
| /s/ Ralph Snyderman, M.D.<br>_____   | Director   |
| Ralph Snyderman, M.D.                |  |

**AXONYX INC.**

**CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2005 and 2004**

F-1

---

AXONYX INC.

Contents

Consolidated Financial Statements:

|   | <u>Page</u> |
|---|-------------|
| <u>Report of Independent Registered Public Accounting Firm</u>  | F-3         |
| <u>Balance sheets as of December 31, 2005 and 2004</u>  | F-4         |
| <u>Statements of operations for each of the years in the three-year period ended December 31, 2005</u>                      | F-5         |
| <u>Statements of changes in stockholders' equity for each of the years in the three-year period ended December 31, 2005</u> | F-6         |
| <u>Statements of cash flows for each of the years in the three-year period ended December 31, 2005</u>                      | F-7         |
| <u>Notes to consolidated financial statements</u>   | F-8         |

F-2

---

**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. as of December 31, 2005 and 2004 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, 2005. 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. as of December 31, 2005 and 2004, 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, 2005 in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Axonyx Inc.'s internal control over financial reporting as of December 31, 2005, based on criteria established in the Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated January 30, 2006 expressed an unqualified opinion on management's assessment and the effective operation of, internal control over financial reporting.

EISNER LLP

New York, New York  
January 30, 2006

## AXONYX INC.

## Consolidated Balance Sheets

|  | December 31,         |                       |
|--|----------------------|-----------------------|
|  | 2005                 | 2004                  |
| <b>ASSETS</b>  |                      |                       |
| Current assets:  |                      |                       |
| Cash and cash equivalents  | \$ 1,638,000         | \$ 10,091,000         |
| Investments  | 56,700,000           | 80,500,000            |
| Accounts receivable  |                      | 229,000               |
| Stock subscriptions receivable   |                      | 2,250,000             |
| Inventories  |                      | 246,000               |
| Other current assets   | 614,000              | 141,000               |
| <b>Total current assets</b>  | <b>58,952,000</b>    | <b>93,457,000</b>     |
| Property, plant and equipment, net   | 49,000               | 116,000               |
| Investment in OXIS   | 4,917,000            |                       |
| Technology for developed products, net   |                      | 6,807,000             |
| Patents and patents pending, net   |                      | 995,000               |
| Security deposits  | 124,000              | 19,000                |
|  | <b>\$ 64,042,000</b> | <b>\$ 101,394,000</b> |
| <b>LIABILITIES</b>   |                      |                       |
| Current liabilities:   |                      |                       |
| Accounts payable   | \$ 4,147,000         | \$ 6,365,000          |
| Accrued expenses   | 1,512,000            | 2,386,000             |
| Note payable   |                      | 160,000               |
| <b>Total current liabilities</b>   | <b>5,659,000</b>     | <b>8,911,000</b>      |
| Outside interest in OXIS   |                      | 5,945,000             |
| <b>Commitments and other matters (notes D&amp;G)</b>   |                      |                       |
| <b>STOCKHOLDERS EQUITY</b>   |                      |                       |
| 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 2005 and 2004, respectively; 53,680,721 and 53,645,518 shares issued and outstanding in 2005 and 2004, respectively |                      |                       |
|  | 54,000               | 54,000                |
| Additional paid-in   | 149,466,000          | 149,150,000           |
| Unearned compensation - stock options  | (15,000)             | (144,000)             |
| Accumulated comprehensive loss   |                      | (14,000)              |
| Accumulated deficit  | (91,122,000)         | (62,508,000)          |
| <b>Total stockholders' equity</b>  | <b>58,383,000</b>    | <b>86,538,000</b>     |
| <b>Total liabilities and stockholders' equity</b>  | <b>\$ 64,042,000</b> | <b>\$ 101,394,000</b> |

Cash and cash equivalents and investments for 2004 have been reclassified to conform to the 2005 presentation (see Note B-3).

See notes to consolidated financial statements



## AXONYX INC.

Consolidated Statements of Operations

|   | Year Ended December 31, |                 |                |
|---|-------------------------|-----------------|----------------|
|   | 2005                    | 2004            | 2003           |
| Revenue   |                         |                 |                |
| Licensing                                       | \$                      | \$ 450,000      | 1,000,000      |
| Product sales                                   | <b>403,000</b>          | 1,825,000       |                |
| Total revenue                                   | <b>403,000</b>          | 2,275,000       | 1,000,000      |
| Cost of product sales                           | <b>210,000</b>          | 1,167,000       |                |
|   | <b>193,000</b>          | 1,108,000       | 1,000,000      |
| Costs and expenses:                             |                         |                 |                |
| Research and development                        | <b>24,621,000</b>       | 23,741,000      | \$ 5,821,000   |
| Sales, general and administrative               | <b>5,143,000</b>        | 8,250,000       | 3,459,000      |
|   | <b>29,764,000</b>       | 31,991,000      | 9,280,000      |
| Loss from operations                            | <b>(29,571,000)</b>     | (30,883,000)    | (8,280,000)    |
| Other income (expenses)                         |                         |                 |                |
| Interest income                                 | <b>2,235,000</b>        | 1,235,000       | 137,000        |
| Foreign exchange                                | <b>(109,000)</b>        | (83,000)        | 37,000         |
| (Loss) gain on issuance of subsidiary stock     | <b>(314,000)</b>        | 1,154,000       |                |
| Equity in loss of OXIS                          | <b>(1,017,000)</b>      |                 |                |
| Other income                                    |                         | 19,000          |                |
| Financing fees                                  |                         | (856,000)       |                |
| Interest expense                                | <b>(2,000)</b>          | (51,000)        |                |
| Net loss before minority interest in subsidiary | <b>(28,778,000)</b>     | (29,465,000)    | (8,106,000)    |
| Outside interest in loss of subsidiary          | <b>164,000</b>          | 685,000         |                |
| Net loss  | <b>(28,614,000)</b>     | (28,780,000)    | (8,106,000)    |
| Comprehensive loss                              |                         |                 |                |
| Foreign currency translation adjustment         |                         | (14,000)        |                |
| Comprehensive loss                              | <b>\$ (28,614,000)</b>  | \$ (28,794,000) | \$ (8,106,000) |
| Net loss per common share                       | <b>\$ (.53)</b>         | \$ (.58)        | \$ (.30)       |
| Weighted average shares - basic and diluted     | <b>53,668,000</b>       | 49,977,000      | 27,207,000     |

See notes to consolidated financial statements





## AXONYX INC.

## Consolidated Statements of Changes in Stockholders' Equity

|  | Common Stock           |           | Additional<br>Paid-in | Unearned<br>Compensation<br>Stock<br>Options | Accumulated<br>Deficit | Accumulated<br>Other<br>Comprehensive<br>Loss | Total<br>Stockholders<br>Equity |
|--|------------------------|-----------|-----------------------|--|------------------------|---|---------------------------------|
|  | Number<br>of<br>Shares | Amount    |                       |  |                        |   |                                 |
| <b>Balance - December 31,<br/>2002</b>   | 23,733,613             | \$ 24,000 | \$ 32,255,000         | \$ (8,000)                                   | \$ (25,622,000)        |   | \$ 6,649,000                    |
| Issuance of common stock<br>and warrants net of<br>expenses                          | 7,706,636              | 8,000     | 24,005,000            |  |                        |   | 24,013,000                      |
| Amortization   |                        |           |                       | 8,000  |                        |   | 8,000                           |
| Issuance of common stock<br>options and warrants for<br>consulting services          |                        |           | 570,000               |  |                        |   | 570,000                         |
| Issuance of common stock<br>for consulting services                                  | 115,000                |           | 205,000               |  |                        |   | 205,000                         |
| Exercise of common stock<br>options and warrants                                     | 2,364,699              | 2,000     | 3,310,000             |  |                        |   | 3,312,000                       |
| Net loss   |                        |           |                       |  | (8,106,000)            |   | (8,106,000)                     |
| <b>Balance - December 31,<br/>2003</b>   | 33,919,948             | \$ 34,000 | \$ 60,345,000         |  | \$ (33,728,000)        |   | \$ 26,651,000                   |
| Issuance of common stock<br>and warrants net of<br>expenses                          | 12,727,106             | 13,000    | 64,731,000            |  |                        |   | 64,744,000                      |
| Issuance of common stock<br>for the acquisition of 52% of<br>OXIS International Inc. | 1,618,061              | 2,000     | 8,192,000             |  |                        |   | 8,194,000                       |
| Issuance of common stock<br>options and warrants for<br>consulting services          |                        |           | 2,264,000             |  |                        |   | 2,264,000                       |
| Issuance of common stock<br>options  |                        |           | 387,000               | (387,000)                                    |                        |   |                                 |
| Exercise of common stock<br>options and warrants                                     | 5,380,403              | 5,000     | 13,231,000            |  |                        |   | 13,236,000                      |
| Amortization   |                        |           |                       | 243,000                                      |                        |   | 243,000                         |
| Foreign currency translation<br>adjustment   |                        |           |                       |  |                        | (14,000)                                      | (14,000)                        |
| Net loss   |                        |           |                       |  | (28,780,000)           |   | (28,780,000)                    |
| <b>Balance - December 31,<br/>2004</b>   | 53,645,518             | \$ 54,000 | \$ 149,150,000        | \$ (144,000)                                 | \$ (62,508,000)        | (14,000)                                      | \$ 86,538,000                   |
| Reduction from change from<br>consolidation of OXIS to<br>equity method              |                        |           |                       |  |                        | 14,000  | 14,000                          |
| Amortization   |                        |           |                       | 129,000                                      |                        |   | 129,000                         |
| Issuance of common stock<br>options for consulting<br>services                       |                        |           | 276,000               |  |                        |   | 276,000                         |
| Modification of common<br>stock options  |                        |           | 20,000                |  |                        |   | 20,000                          |
|  | 35,203                 |           | 20,000                |  |                        |   | 20,000                          |

Edgar Filing: AXONYX INC - Form 10-K

Exercise of common stock  
options and warrants  
Net loss

(28,614,000)

(28,614,000)

**Balance - December 31,  
2005**

53,680,721 \$ 54,000 \$ 149,466,000 \$ (15,000) \$ (91,122,000)

\$ 58,383,000

*See notes to consolidated financial statements*

F-6

## AXONYX INC.

## Consolidated Statements of Cash Flows

|   | Year Ended December 31, |                  |                  |
|---|-------------------------|------------------|------------------|
|   | 2005                    | 2004             | 2003             |
| <b>Cash flows from operating activities:</b>                                |                         |                  |                  |
| Net loss  | \$ (28,614,000)         | \$ (28,780,000)  | \$ (8,106,000)   |
| Adjustments to reconcile net loss to net cash used in operating activities: |                         |                  |                  |
| Depreciation and amortization   | 549,000                 | 889,000          | 16,000           |
| Amortization of deferred financing costs                                    |                         | 772,000          |                  |
| Minority interest in net loss of subsidiary                                 | (164,000)               | (685,000)        |                  |
| Compensation related to common stock issued for services                    |                         | 49,000           |                  |
| Compensation related to options and warrants issued for services            | 425,000                 | 2,551,000        | 783,000          |
| Loss (gain) on issuance of subsidiary stock                                 | 314,000                 | (1,154,000)      |                  |
| Equity loss of OXIS   | 1,017,000               |                  |                  |
| Changes in:   |                         |                  |                  |
| Accounts receivable   | (105,000)               | 38,000           |                  |
| Inventory   | (1,000)                 | 49,000           |                  |
| Other current assets  | (581,000)               | 75,000           |                  |
| Security deposits and other assets  | (105,000)               | 24,000           | 47,000           |
| Accounts payable  | (1,899,000)             | 4,531,000        | 560,000          |
| Accrued expenses  | (38,000)                | 1,250,000        | (135,000)        |
| Accrued stock-based compensation  | (386,000)               | (61,000)         | 404,000          |
| Net cash used in operating activities                                       | (29,588,000)            | (20,452,000)     | (6,431,000)      |
| <b>Cash flows from investing activities:</b>                                |                         |                  |                  |
| Cash acquired in connection with OXIS acquisition                           |                         | 714,000          |                  |
| Costs related to OXIS acquisition   |                         | (52,000)         |                  |
| Reduction in cash due to deconsolidation of OXIS                            | (4,907,000)             |                  |                  |
| Additions to patents  | (48,000)                | (297,000)        |                  |
| Purchase of equipment   | (13,000)                | (89,000)         | (3,000)          |
| Purchases of investments  | (50,450,000)            | (146,475,000)    | (20,050,000)     |
| Proceeds from sales and maturities of investments                           | 74,250,000              | 85,925,000       | 100,000          |
| Net cash provided from (used in) investing activities                       | 18,832,000              | (60,274,000)     | (19,953,000)     |
| <b>Cash flows from financing activities:</b>                                |                         |                  |                  |
| Net proceeds from issuance of common stock and warrants                     | 20,000                  | 68,614,000       | 24,013,000       |
| Net proceeds from exercise of common stock options and warrants             |                         | 13,236,000       | 3,312,000        |
| Collection of stock subscription receivable OXIS                            | 2,250,000               |                  |                  |
| Net proceeds from exercise of common stock options in OXIS                  | 33,000                  | 137,000          |                  |
| Collection of stock subscriptions receivable and cash held in escrow        |                         |                  | 4,868,000        |
| Net cash provided by financing activities                                   | 2,303,000               | 81,987,000       | 32,193,000       |
| <b>Net increase (decrease) in cash and cash equivalents</b>                 | <b>(8,453,000)</b>      | <b>1,261,000</b> | <b>5,809,000</b> |
| Cash and cash equivalents at beginning of period                            | 10,091,000              | 8,830,000        | 3,021,000        |

Edgar Filing: AXONYX INC - Form 10-K

|   |                     |                      |                     |
|---|---------------------|----------------------|---------------------|
| <b>Cash and cash equivalents at end of period</b> | <b>\$ 1,638,000</b> | <b>\$ 10,091,000</b> | <b>\$ 8,830,000</b> |
|---|---------------------|----------------------|---------------------|

---

**Supplemental cash flow disclosures**

|               |          |           |
|---------------|----------|-----------|
| Interest paid | \$ 2,000 | \$ 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 |
|--------------------------------------|--------------|

|   |           |
|---|-----------|
| Minority interest in subsidiary equity transactions | \$ 22,000 |
|---|-----------|

*See notes to consolidated financial statements*

F-7

---

**AXONYX INC.**

**Notes to Consolidated Financial Statements**

**December 31, 2005 and 2004**

**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 or potentially another company with similar rights. 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 patent rights to three main classes of therapeutic compounds designed for the treatment of 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 currently has three compounds in development for AD: Phenserine, a potential symptomatic and disease progression treatment for mild to moderate AD; Posiphen, a potential disease progression treatment for AD, and Bisnorcymserine (BNC), a potential symptomatic treatment for severe AD.

During 2005, the Company evaluated its whole Phenserine development program following the results of the first Phase III trial announced in February and March 2005, the results of the curtailed second and third Phase III trials that were subsequently combined, in September 2005, and the interim analysis of the beta amyloid trial announced in March and July 2005 and the results of additional analyses reported subsequently.

Based on the analysis, the Company determined not to commit further resources to the development of Phenserine given its financial resources and decided to accelerate its marketing package for the out-licensing of Phenserine. The trials to date on Phenserine, including extensive preclinical studies, have provided the Company with a comprehensive set of data. Utilizing this data the Company will explore opportunities for out-licensing Phenserine to a company willing to commit the financial resources necessary to undertake further clinical trials. The Company does not plan to incur any additional development expenses for Phenserine beyond those expenses needed to close the ongoing activities in an orderly fashion.

In January 2006, the Company announced the completion of its ascending single dose Phase I trial with Posiphen, in clinical development for the treatment of AD progression. This double-blind, placebo controlled study of Posiphen in healthy men and women sought to establish well tolerated doses.

BNC is a highly selective butyrylcholinesterase inhibitor. Butyrylcholinesterase is found in high concentration in the plaques taken from individuals who have died from AD. Butyrylcholinesterase appears to have an increasing role with advancing AD and its primary mechanism of action results in a dose dependent reduction of acetylcholine. The initial pre-clinical side effect rate potentially allows higher clinical doses. A secondary mechanism of action is associated with dose dependent reductions of beta amyloid precursor protein (APP) and amyloid beta. BNC, the lead compound from the Company's butyrylcholinesterase family, is currently in full pre-Investigational New Drug (IND) development and an IND submission is planned for second quarter of 2006, followed by the potential to initiate Phase I clinical trials thereafter.

As described in Note K, Subsequent Events, the Company announced in January 2006 that it had granted to Daewoong Pharmaceutical Company Ltd. an exclusive license for Phenserine for the South Korean Market.

As of December 31, 2005, 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.

**AXONYX INC.**  
**Notes to Consolidated Financial Statements**  
**December 31, 2005 and 2004**

**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 The Netherlands. 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 through February 28, 2005. The Company's ownership in OXIS was reduced to 34% on December 31, 2004 as the result of a third party financing by OXIS, however, the accounts of OXIS continued to be consolidated as the Company controlled the board of directors through a majority of the OXIS board seats which enabled it to effectively control significant decisions made in the ordinary course of business. 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 had a majority of the seats on the OXIS Board, no longer controlled significant decisions, and, beginning March 1, 2005, OXIS is no longer consolidated but rather accounted for using the equity method.

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.

**[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 at December 31, 2004.

**[3] Investments:**

During the quarter ended September 30, 2005 the Company reclassified the majority of what was previously classified as cash and cash equivalents to investments. The Company follows FASB 115 in determining the appropriate classification for cash equivalents and investments. The Company has invested in auction rates securities (ARS) that are held as investments available-for-sale. After the initial issuance of these securities, the interest rate is reset periodically. The Company invests in ARS that reset as to interest rate every 28 days.

The Company has determined that auction rate securities should be classified as investments because the stated or contractual maturities are generally 20 to 30 years. From an economic viewpoint, these securities are priced and traded as short term investments because of the interest reset feature. Accordingly, the Company has reclassified all such auction rate securities as investments for all periods presented including \$80,500,000 as of December 31, 2004. Cash and cash equivalents and investments as of March 31, 2005 and June 30, 2005, as reclassified, are summarized as follows:

|                           | <u>March 31, 2005</u> | <u>June 30, 2005</u> |
|---------------------------|-----------------------|----------------------|
| Cash and cash equivalents | \$ 4,741,000          | \$ 5,505,000         |
| Investments               | 71,200,000            | 64,800,000           |

**[4] Accounts Receivable:**

Accounts receivable at December 31, 2004 relates to OXIS and is carried 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.

**AXONYX INC.**  
**Notes to Consolidated Financial Statements**  
**December 31, 2005 and 2004**

**[5] Inventory:**

Inventory at December 31, 2004 relates to OXIS and is stated at the lower of cost or market. Cost has been determined by using the first-in, first-out method. Inventory at December 31, 2004 consisted of the following:

|                  | <u>2004</u>       |
|------------------|-------------------|
| Raw materials    | \$ 121,000        |
| Work in progress | 23,000            |
| Finished goods   | 102,000           |
|                  | <u>          </u> |
| Total            | \$ 246,000        |

**[6] 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, 2005, 2004 and 2003 was \$19,000, \$38,000 and \$16,000, respectively.

Property, plant and equipment at December 31, 2005 and 2004, consisted of the following:

|   | <u>2005</u>       | <u>2004</u>       |
|---|-------------------|-------------------|
| Furniture and office equipment            | \$ 141,000        | \$ 207,000        |
| Laboratory and manufacturing equipment    |                   | 3,000             |
|   | <u>          </u> | <u>          </u> |
| Property, plant and equipment, at cost    | 141,000           | 210,000           |
| Accumulated depreciation and amortization | (92,000)          | (94,000)          |
|   | <u>          </u> | <u>          </u> |
| Property, plant and equipment, net        | \$ 49,000         | \$ 116,000        |

**[7] Research and development:**

Research and development costs are expensed as incurred.

**[8] 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.

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

**[9] Fair value of financial instruments:**

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

**[10] Revenue recognition:**

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

F-10

---



**AXONYX INC.**

**Notes to Consolidated Financial Statements**

**December 31, 2005 and 2004**

recognized upon execution of the license agreement. Revenue from the achievement of milestone events stipulated in the agreements are recognized when the milestone is achieved. Royalties are 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.

**[11] 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 value based method for non-employee awards and has elected to continue to apply the provisions of APB Opinion 25 and provide the disclosures required by SFAS No. 123 and SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. The following table illustrates the effect on net loss and loss per share if the fair value based method had been applied to all awards:

F-11

---

**AXONYX INC.**  
**Notes to Consolidated Financial Statements**  
**December 31, 2005 and 2004**

**[11] Stock-based compensation: (continued)**

|  | Year Ended December 31, |                 |                 |
|--|-------------------------|-----------------|-----------------|
|  | 2005                    | 2004            | 2003            |
| Reported net loss attributable to common stockholders                          | \$ (28,614,000)         | \$ (28,780,000) | \$ (8,106,000)  |
| Stock-based employee compensation included in net loss                         | 129,000                 | 243,000         |                 |
| Stock-based employee compensation determined under the fair value based method | (2,451,000)             | (3,207,000)     | (2,515,000)     |
| Pro forma net loss   | \$ (30,936,000)         | \$ (31,744,000) | \$ (10,621,000) |
| Loss per common share (basic and diluted):                                     |                         |                 |                 |
| As reported  | \$ (.53)                | \$ (.58)        | \$ (.30)        |
| Pro forma  | (.58)                   | (.64)           | (.39)           |

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, |             |              |
|---|-------------------------|-------------|--------------|
|   | 2005                    | 2004        | 2003         |
| Risk-free interest rate   | 3.77%-4.33%             | 2.79%-3.60% | 2.27%- 3.27% |
| Expected dividend yield   | 0%                      | 0%          | 0%           |
| Expected life   | 10 years                | 5-10 years  | 5 - 10 years |
| Expected volatility   | .94 - .97               | .90 - .95   | .88 - .95    |
| Weighted average grant-date fair value of options granted during the period (including non-employees) | \$1.03                  | \$4.64      | \$1.82       |

**[12] 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, 2005, 2004, and 2003, potential common shares aggregating 12,428,000, 12,364,000 and 13,540,000, respectively, were excluded in computing the per share amounts.

**[13] Concentration of credit risk:**

Financial instruments which potentially subject the Company to concentration of credit risks consist principally of cash and cash equivalents and investments. The Company primarily holds its cash and cash equivalents and investments in two money market brokerage accounts and commercial paper. In addition, as of December 31, 2005 and 2004, the Company maintained approximately \$358,000 and \$515,000, 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.

F-12

---

**AXONYX INC.**

**Notes to Consolidated Financial Statements**

**December 31, 2005 and 2004**

**[14] 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. Since the adoption of the equity method of accounting for OXIS effective March 1, 2005, the OXIS related long lived assets are not consolidated with the Company. Prior to the adoption of equity accounting, in accordance with SFAS No. 144, the Company periodically reviewed 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.

**[15] 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.

**[16] 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 \$1,250,000 and \$772,000 as of December 31, 2005 and 2004, respectively. Patents are being amortized on a straight-line basis over the shorter of the remaining life of the patent or ten years. At December 31, 2004, a total of \$865,000 of patents pending approval was not being amortized by OXIS. Accumulated amortization as of December 31, 2005 was \$35,000.

**[17] Equity Method of Accounting for Investments in Common Stock**

Effective March 1, 2005, the Company accounted for its investment in OXIS under the equity method of accounting following accounting principles bulletin (APB) No. 18. An impairment charge would be required if the company determined that any reduction in the OXIS market value over the carrying value was other than temporary. As at December 31, 2005, no such charge was deemed necessary. The market value of OXIS common stock was \$0.26 per share as of December 31, 2005 (closing bid price of \$0.30 per share as of March 15, 2006).

**[18] 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.

In changing from the consolidation of OXIS at December 31, 2004 to the equity method the Company determined that a correction was required in the calculation of the gain on subsidiary stock under SEC Staff Accounting Bulletin No. 51. The gain resulted from the issuance of shares by OXIS at December 31, 2004 in connection with a private placement financing. The correction has been effected by a \$398,000 reduction in the carrying value of the investment in OXIS with a corresponding reduction in the loss on issuance stock for the year ended December 31, 2005.

The correction was reflected in the quarter ended March 31, 2005 in accordance with the provisions of Accounting Principles Board Opinion No. 28, Interim Financial Reporting as it is not material to either the 2004 results of operations, the estimated full year 2005 results of operations or to the trend of operations.

**AXONYX INC.****Notes to Consolidated Financial Statements****December 31, 2005 and 2004****NOTE C NEW ACCOUNTING PRONOUNCEMENTS**

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections - A Replacement Of APB Opinion No. 20 AND FASB Statement No. 3 (SFAS 154). SFAS 154 requires retrospective application to prior periods financial statements for changes in accounting principle. SFAS 154 also requires that a change in depreciation, amortization, or depletion method for long-lived, non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The implementation of SFAS 154 is not expected to have a material impact on our results of operations, financial position or cash flows.

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 supersedes 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. The impact of adopting SFAS 123R cannot be currently estimated since it will depend on share based payments granted in the future. However, had the Company adopted SFAS 123R in prior periods, the impact would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss per share in Note B[11].

**NOTE D - 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 AD 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 annual net sales related to products for human use covered and 2% thereafter under the agreement with minimum annual royalty payments of \$150,000 beginning in 2004 through the expiration or termination of the agreement upon the later of the eighth anniversary of first commercial sale of a product covered by the license, on a country-by-country basis, and the date of the last to expire patent covered by the license (2015). In 2005, the Company paid NYU its minimum royalty payment of \$150,000 for 2005 and reimbursed NYU for \$2,000 relating to patent costs. 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 for \$36,000 relating to patent costs. Through December 31, 2005, the Company has paid \$1,572,000 to NYU under the agreement. In addition, in connection with the agreement entered into with NYU and its scientists, the Company's granted additional shares of its 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.

**AXONYX INC.**

**Notes to Consolidated Financial Statements**

**December 31, 2005 and 2004**

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 had been sublicensed to Serono (see Note D-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, 2005, the Company has paid \$110,000 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.

The Company is negotiating a re-acquisition of these rights from Serono and an option to license on a non-exclusive basis, certain Serono patents, technology and know-how related to AIPs and PIPs. If the Company exercises this option and acquires the license, it would be obligated to pay to Serono an up-front payment and under certain circumstances, additional milestone payments and royalties would be due.

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] Research and Development Contracts:**

For the year ended December 31, 2005, the Company incurred significant research and development expenses primarily attributable to the 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 \$4,662,000 in 2006.



**AXONYX INC.**

**Notes to Consolidated Financial Statements**

**December 31, 2005 and 2004**

**NOTE E - INCOME TAXES**

At December 31, 2005, the Company has available a Federal net operating loss carryforward of approximately \$28,290,000, expiring through 2025, that may be used to offset future federal taxable income. At December 31, 2005, the Company also has a research and development credit carryforward of approximately \$2,371,000 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, 2005 there are \$56,908,000 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, 2005, and 2004, the Company has deferred tax assets of approximately \$41,376,000 and \$27,818,000, respectively. The deferred tax asset at December 31, 2005 is comprised of the tax effect of the net operating loss carryforwards (\$12,951,000), the timing differences (\$23,897,000 for capitalized research and development expenses and \$2,156,000 for stock-based compensation) and the research and development credit carryforwards (\$2,371,000). 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 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 \$13,558,000, \$13,557,000, and \$3,778,000 during 2005, 2004 and 2003, respectively, has been provided for the full amount of the deferred tax asset.

**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. The registration rights agreement associated with that private placement provides for liquidated damages of 1.5% of the aggregate purchase price for the first month and 2% for each subsequent month if the Company failed to register such shares and warrant shares or maintain the effectiveness of such registration. The registration rights agreement further provides for interest at 18% per annum for the failure by the Company to pay such liquidated damages if they were to be due.

During 2003, the Company received proceeds of \$3,312,000 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. The registration rights agreement associated with that private placement provides for liquidated damages of 1.5% of the aggregate purchase price for the first month and 2% for each subsequent month if the Company failed to register such shares and warrant shares or maintain the effectiveness of such registration.





**AXONYX INC.****Notes to Consolidated Financial Statements****December 31, 2005 and 2004**

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. The registration rights agreement associated with that private placement provides for liquidated damages of 1% of the aggregate purchase price for the first month and 1.5% for each subsequent month if the Company failed to register such shares and warrant shares or maintain the effectiveness of such registration, subject to a maximum of 10%.

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.

The Company accounts for the registration rights agreements as separate freestanding instruments and accounts for the liquidated damages provisions as a derivative liability subject to SFAS No. 133. The estimated fair value of the derivative liability is based on estimates of the probability and costs of cash penalties expected to be incurred and such estimates are revalued at each balance sheet date with changes in value recorded in other income. As of December 31, 2005 and 2004 the Company has estimated the fair values of these derivative liabilities to be nominal and accordingly no liability has been recorded. There were no changes to the estimated fair value during the years ended December 31, 2005, 2004 and 2003.

**[2] Warrants:**

At December 31, 2005, outstanding warrants to acquire shares of the Company's common stock are as follows:

| Number of<br>Shares | Exercise<br>Price | Expiration<br>Date |
|---------------------|-------------------|--------------------|
| 954,000             | \$ 8.50           | May 6, 2009        |
| 2,529,000           | 3.50              | September 11, 2008 |
| 2,967,000           | 7.25              | January 8, 2009    |
| 24,000              | 6.81              | February 13, 2006  |
| 433,000             | .69               | December 31, 2007  |
| 200,000             | 1.00              | January 15, 2008   |
| 7,107,000           |                   |                    |

The weighted average exercise price of warrants outstanding at December 31, 2005 was \$5.51 and the weighted average remaining contractual life of the warrants was 2.85 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 non-statutory 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 stock may not exceed five years and their exercise price may not

## Edgar Filing: AXONYX INC - Form 10-K

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, as amended, provides for the granting of options to purchase up to 2,000,000 shares of common stock and pursuant to which officers, directors, advisors and consultants are eligible to receive incentive and/or non-statutory stock options. Incentive stock options granted under the 2000 Plan are exercisable for a

F-17

---

**AXONYX INC.****Notes to Consolidated Financial Statements  
December 31, 2005 and 2004**

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 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.

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, 2005, 2004 and 2003, the Company granted none, 497,000 and 300,000 options, respectively, to consultants and recorded expenses (credit) of \$(90,000), \$2,264,000 and \$570,000, respectively, relating to the vested portion of these options. Accrued expenses at December 31, 2005, 2004, and 2003 include an additional \$12,000, \$399,000 and \$460,000, 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, |                                 |           |                                 |           |                                 |
|------------------------------------|-------------------------|---------------------------------|-----------|---------------------------------|-----------|---------------------------------|
|                                    | 2005                    |                                 | 2004      |                                 | 2003      |                                 |
|                                    | Shares                  | Weighted Average Exercise Price | Shares    | Weighted Average Exercise Price | Shares    | Weighted Average Exercise Price |
| Options at beginning of year       | 984,000                 | \$ 5.96                         | 1,375,000 | \$ 5.72                         | 1,790,000 | \$ 6.37                         |
| Options issued                     |                         |                                 |           |                                 | 50,000    | 1.11                            |
| Options exercised                  |                         |                                 | (50,000)  | .02                             | (50,000)  | .02                             |
| Options forfeited                  | (40,000)                | 8.98                            | (341,000) | 5.83                            | (415,000) | 8.68                            |
| Options at end of year             | 944,000                 | 5.84                            | 984,000   | 5.96                            | 1,375,000 | 5.72                            |
| Options exercisable at end of year | 928,000                 | 6.34                            | 949,000   | 6.53                            | 1,313,000 | 5.77                            |

The 1998 Plan terminated on January 15, 2003.

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

F-18

**AXONYX INC.**  
**Notes to Consolidated Financial Statements**  
**December 31, 2005 and 2004**

|                                    | Year Ended December 31, |                        |                  |                        |                  |                        |
|------------------------------------|-------------------------|------------------------|------------------|------------------------|------------------|------------------------|
|                                    | 2005                    |                        | 2004             |                        | 2003             |                        |
|                                    | Shares                  | Weighted Average Price | Shares           | Weighted Average Price | Shares           | Weighted Average Price |
| Options at beginning of year       | 3,450,000               | \$ 4.21                | 2,738,000        | \$ 2.86                | 1,671,000        | \$ 3.45                |
| Options issued                     | 810,000                 | 1.16                   | 1,566,000        | 5.39                   | 1,107,000        | 2.08                   |
| Options exercised                  | (20,000)                | 1.00                   | (633,000)        | 1.91                   |                  |                        |
| Options forfeited                  | (106,000)               | 5.01                   | (221,000)        | 2.54                   | (40,000)         | 5.54                   |
| Options at end of year             | <u>4,134,000</u>        | <u>3.60</u>            | <u>3,450,000</u> | <u>4.21</u>            | <u>2,738,000</u> | <u>2.86</u>            |
| Options exercisable at end of year | <u>3,116,000</u>        | <u>3.67</u>            | <u>2,073,000</u> | <u>3.85</u>            | <u>1,537,000</u> | <u>3.25</u>            |

As of December 31, 2005, 2,689,000 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, |                        |                |                        |                |                        |
|------------------------------------|-------------------------|------------------------|----------------|------------------------|----------------|------------------------|
|                                    | 2005                    |                        | 2004           |                        | 2003           |                        |
|                                    | Shares                  | Weighted Average Price | Shares         | Weighted Average Price | Shares         | Weighted Average Price |
| Options at beginning of year       | 343,000                 | \$ 4.51                | 375,000        | \$ 4.41                | 129,000        | \$ 7.81                |
| Options issued                     |                         |                        |                |                        | 275,000        | 3.06                   |
| Options exercised                  |                         |                        | (32,000)       | 3.41                   |                |                        |
| Options forfeited                  | (100,000)               | 8.31                   |                |                        | (29,000)       | 6.72                   |
| Options at end of year             | <u>243,000</u>          | <u>3.01</u>            | <u>343,000</u> | <u>4.51</u>            | <u>375,000</u> | <u>4.41</u>            |
| Options exercisable at end of year | <u>243,000</u>          | <u>3.01</u>            | <u>305,000</u> | <u>4.74</u>            | <u>207,000</u> | <u>5.63</u>            |

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

F-19

---

**AXONYX INC.**  
**Notes to Consolidated Financial Statements**  
**December 31, 2005 and 2004**

As of December 31, 2005

| Range of Exercise Prices | Options Outstanding |   | Options Exercisable             |                  |                                 |
|--------------------------|---------------------|---|---------------------------------|------------------|---------------------------------|
|                          | Shares              | Weighted Average Remaining Contractually (in years) | Weighted Average Exercise Price | Shares           | Weighted Average Exercise Price |
| \$.02-\$.84              | 162,000             | 5.06  | \$ .58                          | 152,000          | \$ .56                          |
| \$1.00 - \$1.35          | 1,069,000           | 8.52  | 1.15                            | 433,000          | 1.16                            |
| \$2.07 - \$3.16          | 1,446,000           | 4.65  | 2.94                            | 1,446,000        | 2.94                            |
| \$3.61 - \$6.68          | 1,654,000           | 5.31  | 4.54                            | 1,465,000        | 4.56                            |
| \$7.00 - \$8.12          | 736,000             | 6.91  | 7.43                            | 536,000          | 7.58                            |
| \$9.50 - \$11.50         | 254,000             | 4.47  | 10.31                           | 254,000          | 10.31                           |
|                          | <u>5,321,000</u>    | <u>5.95</u>   | <u>3.98</u>                     | <u>4,286,000</u> | <u>4.24</u>                     |

**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.

Rent expense was approximately \$155,000, \$294,000 and \$112,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

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

Several lawsuits against the Company and certain directors and officers were filed, which have been consolidated into a single class action lawsuit. The class action plaintiffs allege that the defendants knowingly or recklessly made false or misleading statements regarding the effectiveness of Phenserine, which they allege had the effect of artificially inflating the price of our common stock.

There is also a derivative suit pending against current and former directors and officers of the Company alleging that the defendants breached their duties to the Company and misused inside information regarding clinical trials of Phenserine. This action has been stayed pending further developments in the class action.

The complaints seek unspecified damages. We believe that the complaints are without merit and intend to defend these lawsuits vigorously. However there can be no assurance that we will prevail in these actions.

**NOTE H - EMPLOYEE BENEFIT PLANS**

In January 2005, the Company adopted a 401-K defined contribution profit-sharing plan covering its U.S. employees. Contributions to the plan are based on employer contributions as determined by the Company and allowable discretionary contributions, as determined by the Company's Board of Directors, subject to certain limitations. Contributions by the Company to this plan amounted to \$23,474 for 2005.

**AXONYX INC.****Notes to Consolidated Financial Statements  
December 31, 2005 and 2004****NOTE I - Quarterly Results (Unaudited)**

|  | Quarter Ended |                |                |                |
|--|---------------|----------------|----------------|----------------|
|  | March 31,     | June 30,       | September 30,  | December 31,   |
| <b>2005:</b>                           |               |                |                |                |
| Revenue                                | \$ 403,000    |                |                |                |
| Net loss                               | (10,433,000)  | \$ (8,179,000) | \$ (5,687,000) | \$ (4,315,000) |
| Loss per share - basic and diluted (a) | (0.19)        | (0.15)         | (0.11)         | (0.08)         |
| <b>2004</b>                            |               |                |                |                |
| 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)         |

- (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 J 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 then Chairman and 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. 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 taxes (1)                    | (3,011,000)         |
| Deferred taxes (2)                    | 3,011,000           |
|                                       | <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.





**AXONYX INC.**

**Notes to Consolidated Financial Statements**

**December 31, 2005 and 2004**

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 outside 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.

The following represents unaudited summary information of OXIS, which is accounted for under the equity method. Shown below are (a) total assets and total liabilities for OXIS as of December 31, 2005 and (b) revenue and net loss for OXIS for the ten months ended December 31, 2005.

|                    |              |
|--------------------|--------------|
| Total assets       | \$ 7,806,000 |
| Total liabilities  | 4,268,000    |
| Revenue            | 2,094,000    |
| Net loss           | (2,929,000)  |
| 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 tables present information about the Company's two operating segments:

|   | <u>Axonyx Inc.</u> | <u>OXIS<br/>Int'l Inc.</u> | <u>Total</u>    |
|---|--------------------|----------------------------|-----------------|
| <i>Year ended December 31, 2005</i>                             |                    |                            |                 |
| Revenue including minority interest                             |                    | \$ 403,000                 | \$ 403,000      |
| Segment loss  | \$ (27,053,000)    | \$ (1,561,000)             | \$ (28,614,000) |
| Segment assets including minority interest at December 31, 2005 | \$ 64,042,000      | \$                         | \$ 64,042,000   |

Edgar Filing: AXONYX INC - Form 10-K

*Year ended December 31, 2004*

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| 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  |

F-22

**AXONYX INC.**

**Notes to Consolidated Financial Statements**

**December 31, 2005 and 2004**

**NOTE K SUBSEQUENT EVENTS**

In January 2006 the Company announced that it had granted to Daewoong Pharmaceutical Company Ltd. (Daewoong) an exclusive license for the use of Phenserine in the South Korean market. Under the terms of the agreement Daewoong, at its own costs, undertakes to pursue the product development and regulatory work necessary for a New Drug Application (NDA) (or its equivalent) in South Korea with respect to Phenserine for the treatment of AD. The financial terms of the deal include royalty payments to Axonyx based on sales of Phenserine by Daewoong in the South Korean market.

F-23

---

**AXONYX INC.**

**Exhibits filed with Annual Report on Form 10-K  
for the fiscal year ended December 31, 2005**

- 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

III-24

---