AXONYX INC Form S-8 September 01, 2004

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

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FORM S-8
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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AXONYX INC.

(Exact Name of Registrant as Specified in Its Charter)

NEVADA
(State or Other Jurisdiction of Incorporation or Organization)

86-0883978 (I.R.S. Employer Identification No.)

500 SEVENTH AVENUE, 10th FLOOR,
NEW YORK, NEW YORK
(Address of Principal Executive Offices)

10018 (Zip Code)

AXONYX INC. 2000 STOCK OPTION PLAN AS AMENDED AND RESTATED AS OF APRIL 18, 2002

AXONYX INC. SECOND AMENDED AND RESTATED 2000 STOCK OPTION PLAN

1997 RICHARD SALVADOR STOCK OPTION PLAN (Full Title of the Plans)

Marvin S. Hausman, M.D., Chairman & Chief Executive Officer
500 Seventh Avenue
10th Floor

New York, New York 10018 (212) 645-7704

(Name, Address and Telephone Number of Agent for Service)

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## CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price per Share	Propo Maxim Aggreg Offer Pric
common stock, par value \$0.001 per share (3) common stock, par value \$0.001 per share (4)	675,000 4,000,000	\$4.23 (2) \$4.23 (2)	\$ 2,855, \$16,920,
common stock, par value \$0.001 per share (5)	50,000	\$0.02	\$ 1,

common stock, par value \$0.001 per share (6) 100,000 \$4.23 (2) \$ 423,

Total 4,825,000

(1) This Registration Statement shall also cover any additional shares of common stock which become issuable under the Registrant's option plans covered hereby by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the Registrant's receipt of consideration which results in an increase in the number of outstanding shares of the Registrant's common stock.

- (2) Calculated solely for the purpose of determining the registration fee pursuant to Rule 457(h) based upon the average of the high and low sales prices of the Registrant's common stock on August 26, 2004, as reported on NASDAQ.
- (3) shares underlying options that may be granted in the future pursuant to the Registrant's 2000 Stock Option Plan, as Amended and Restated as of April 18, 2002
- (4) shares underlying options that may be granted in the future pursuant to the Registrant's Second Amended and Restated 2000 Stock Option Plan as of June 22, 2004
- (5) shares underlying unexercised options previously granted pursuant to the Registrant's 1997 Richard Salvador Stock Option Plan

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(6) shares previously issued upon the exercise of options granted pursuant to the Registrant's 2000 Stock Option Plan, as Amended and Restated as of April 18, 2002, and the Registrant's 1997 Richard Salvador Stock Option Plan

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## PART I

INFORMATION REQUIRED IN THE SECTION 10(A) PROSPECTUS

## EXPLANATORY NOTE

As permitted by the rules of the Securities and Exchange Commission, this Registration Statement omits the information specified in Part I of Form S-8. The documents containing the information specified in Part I will be delivered to the participants in the plans covered by this Registration Statement as required by Rule 428(b) promulgated under the Securities Act of 1933, as amended. Such documents are not being filed with the Securities and Exchange Commission as part of this Registration Statement or as prospectuses or prospectus supplements pursuant to Rule 424 of such Act.

## PART II

INFORMATION REQUIRED IN THE REGISTRATION STATEMENT

ITEM 3. INCORPORATION OF DOCUMENTS BY REFERENCE

Axonyx Inc. hereby incorporates by reference into this Registration Statement the following documents previously filed with the Securities and Exchange Commission ("SEC"):

- 1. The Quarterly Reports on Form 10-Q for the quarter ended March 31, 2004, filed with the SEC on May 14, 2004, and for the quarter ended June 30, 2004, filed with the SEC on August 11, 2004;
- 2. The Annual Report on Form 10-K for the year ended December 31, 2003, filed with the SEC on March 30, 2004;
- 3. The Current Reports on Form 8-K filed with the SEC on January 12, 2004, January 20, 2004 (as amended on Form 8-K/A filed with the SEC on March 30, 2004), May 5, 2004, June 4, 2004, June 4, 2004 and June 10, 2004; and
- 4. The description of our common stock set forth in the Amendment No. 1, Registration Statement on Form 10-SB, filed with the SEC on August 10, 1999.

All reports and definitive proxy or information statements filed pursuant to Section 13(a), 13(c), 14 and 15(d) of the Securities Exchange Act of 1934 (the "1934 Act"), after the date of this Registration Statement and prior to the filing of a post-effective amendment which indicates that all securities offered hereby have been sold or

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which deregisters all securities then remaining unsold shall be deemed to be incorporated by reference into this Registration Statement and to be a part hereof from the date of filing of such documents. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained herein or in any subsequently filed document which also is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Registration Statement.

ITEM 4. DESCRIPTION OF SECURITIES

Not applicable.

ITEM 5. INTERESTS OF NAMED EXPERTS AND COUNSEL

Not applicable.

## ITEM 6. INDEMNIFICATION OF DIRECTORS AND OFFICERS

The Nevada General Corporation Law allows us to indemnify our officers and directors from liability incurred by reason of the fact that he or she is or was an officer or director of the corporation. We may authorize such indemnification if we determine that it is proper under the circumstances. This determination can be authorized based on a vote of our stockholders, by a majority vote of a quorum of directors who were not parties to the relevant legal action, or under certain circumstances, by independent legal counsel in a written opinion. The indemnification can include, but is not limited to, reimbursement of all fees, including amounts paid in settlement and attorney's fees actually and reasonably incurred, in connection with the defense or settlement of any action or suit by the officer or director. The Restated Articles of Incorporation and the By-Laws of Axonyx Inc. contain provisions relating to indemnification of officers and

directors. Those provisions appear below.

Article X of the Articles of Incorporation of Axonyx Inc. provides as follows:

The personal liability of the directors of the corporation is hereby eliminated to the fullest extent permitted by the provisions of the Nevada Revised Statutes of the State of Nevada, as the same may be amended and supplemented. The corporation shall indemnify any person who incurs expenses by reason of the fact that he or she is or was an officer, director, employee or agent of the corporation. This indemnification shall be mandatory on all circumstances in which indemnification is permitted by law.

Article VI of the By-Laws of Axonyx Inc. provides as follows:

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The corporation shall, to the maximum extent and in the manner permitted by the Nevada Revised Statutes, indemnify each of its directors and officers against expenses (including attorneys' fees), judgments, fines, settlements, and other amounts actually and reasonably incurred in connection with any proceeding, arising by reason of the fact that such person is or was an agent of the corporation. For purposes of this Section 6.1, a "director" or "officer" of the corporation includes any person (i) who is or was a director or officer of the corporation, (ii) who is or was serving at the request of the corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, or (iii) who was a director or officer of a corporation which was a predecessor corporation of the corporation or of another enterprise at the request of such predecessor corporation.

The corporation shall have the power, to the maximum extent and in the manner permitted by the Nevada Revised Statutes, to indemnify each of its employees and agents (other than directors and officers) against expenses (including attorneys' fees), judgments, fines, settlements, and other amounts actually and reasonably incurred in connection with any proceeding, arising by reason of the fact that such person is or was an agent of the corporation. For purposes of this Section 6.2, an "employee" or "agent" of the corporation (other than a director or officer) includes any person (i) who is or was an employee or agent of the corporation, (ii) who is or was serving at the request of the corporation as an employee or agent of another corporation, partnership, joint venture, trust or other enterprise, or (iii) who was an employee or agent of a corporation which was a predecessor corporation of the corporation or of another enterprise at the request of such predecessor corporation.

The corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against him and incurred by him in any such capacity, or arising out of his status as such, whether or not the corporation would have the power to indemnify him against such liability under the provisions of the Nevada Revised Statutes.

We have purchased and maintained insurance covering our officers and directors for the purpose of covering indemnification expenses.

At present, there is no pending litigation or proceeding involving a director, officer, employee or agent of our company as to which indemnification is being sought.

## ITEM 7. EXEMPTION FROM REGISTRATION CLAIMED

Not applicable.

## ITEM 8. EXHIBITS

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Exhibit No.	Description of Document
4.1*	Restated Articles of Incorporation of Axonyx Inc. dated July 23, 2000, as amended by the Certificate of Amendment of Restated Articles of Incorporation dated June 28, 2004
4.2**	By-Laws of Axonyx Inc.
4.3***	Axonyx Inc. Second Amended and Restated 2000 Stock Option Plan
4.40	Axonyx Inc. Second Amended and Restated 2000 Stock Option Plan
4.5	1997 Richard Salvador Stock Option Plan
5.1	Opinion of Ehrenreich Eilenberg & Krause LLP
23.1	Consent of Eisner LLP
23.2	Consent of Ehrenreich, Eilenberg & Krause LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included in the signature page)

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- \* Incorporated by reference to the corresponding exhibits in the Form 10-QSB previously filed by the Company on August 14, 2000 and the Quarterly Report on Form 10-Q for the quarter ended June 30, 2004 previously filed by the Company on August 11, 2004.
- \*\* Incorporated by reference to the corresponding exhibit in the Registration Statement on Form 10-SB previously filed by the Company on March 17, 1999 (File no. 000-25571).
- \*\*\* Incorporated by reference to the corresponding exhibit in the Schedule 14A previously filed by the Company on May 20, 2002.
- @ Incorporated by reference to the corresponding exhibit in the Schedule 14A previously filed by the Company on May 14, 2004.

## ITEM 9. UNDERTAKINGS

A. The undersigned Registrant hereby undertakes: (1) to file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement: (i) to include any prospectus required by Section 10(a)(3) of the Securities Act, (ii) to reflect in the prospectus any facts or events arising

after the effective date of this Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this Registration Statement and (iii) to include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in this Registration Statement; provided, however, that clauses (1)(i) and (1)(ii) shall not apply if the information required to be included in a post-effective amendment by those clauses is contained in periodic reports filed with or furnished to the SEC by the Registrant pursuant to Section 13 or Section 15(d) of the 1934 Act that are incorporated by reference into this Registration Statement; (2) that for the purpose of determining any liability under the Securities Act each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof and (3) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

- B. The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the 1934 Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the 1934 Act) that is incorporated by reference in this Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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## EXPLANATORY NOTE

The Reoffer Prospectus being filed with this Registration Statement has been prepared in accordance with the requirements of General Instruction C to Form S-8 and Part I of S-3, and may be used for reofferings of Axonyx Inc.'s common stock that were acquired or that may be acquired in the future under our option plans by the persons named in the Reoffer Prospectus.

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REOFFER PROSPECTUS

#### AXONYX INC.

#### COMMON STOCK

This Reoffer Prospectus relates to the sale of up to 100,000 shares of common stock of Axonyx Inc. by one or more of the selling securityholders identified in this Reoffer Prospectus or in a supplement to this Reoffer Prospectus. All of these shares (i) were previously issued to the selling securityholders, or (ii) are authorized and unissued shares of our common stock that may be acquired by the selling securityholders, pursuant to the exercise of options that were granted to them in their capacity as employees and consultants of our company by our Board of Directors under the option plans. We will not receive any of the proceeds from the sales of these shares by the selling securityholders. However, we will receive the proceeds from any exercise of stock options granted under the option plans.

From time to time, for their own accounts, selling securityholders may sell shares directly to purchasers or through agents, brokers, dealers or underwriters. Such agents, brokers, dealers or underwriters may receive concessions or commissions that exceed customary commissions from the selling securityholders or purchasers of the shares. Sales of the shares may be made in one or more transactions through the Nasdaq Small Cap Market, in the over-the-counter market, in privately negotiated transactions or otherwise. Sales may be made at the market price at the time of sale, a price related to the market price or a negotiated price. Our common stock is quoted on the Nasdaq Small Cap Market under the symbol AXYX.

Any brokers, dealers or agents that participate in the distribution of the shares may be deemed to be underwriters and any commissions received by them and any profit on the resale of such shares positioned by them might be deemed to be underwriting discounts and commissions under the Securities Act of 1933.

We will pay all costs and expenses incurred by our company in connection with the registration of the shares under the Securities Act of 1933. The selling securityholders will pay the costs associated with any sale of shares, including any discounts, commissions and applicable transfer taxes.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved these securities or passed upon the accuracy or adequacy of this Reoffer Prospectus. Any representation to the contrary is a criminal offense.

The date of this Reoffer Prospectus is August 27, 2004.

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You should rely only on the information contained in this document or to which we have referred you. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information contained in this document may only be accurate on the date of this document. This Reoffer Prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, in any state where the offer or sale is prohibited. Neither the delivery of this Reoffer Prospectus, nor any sale made under this Reoffer Prospectus shall, under any circumstances, imply that the information in this Reoffer Prospectus is correct

as of any date after the date of this Reoffer Prospectus.

#### FORWARD-LOOKING STATEMENTS

This Reoffer Prospectus contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended. All statements, other than statements of historical facts, included in, or incorporated by reference into this Reoffer Prospectus, are forward-looking statements. In addition, when used in this document, the words "anticipate", "estimate", "project", and similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to various risks or uncertainties and assumptions. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, estimated or projected. Although we believe that the expectations reflected in these forward-looking statements are reasonable, we cannot assure you that such expectations will prove to have been correct. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under "Risk Factors," that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of these statements. We are under no duty to update any of the forward-looking statements after the date of this Reoffer Prospectus or to conform these statements to actual results unless required by law.

#### AVAILABLE INFORMATION

Axonyx Inc. is subject to the informational requirements of the Exchange Act and, accordingly, files reports, proxy statements and other information with the Commission. Such reports, proxy statements and other information may be inspected and copied at the Commission's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. The Commission

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maintains a Web site at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Commission.

Axonyx Inc. has filed with the Commission a registration statement on Form S-8 under the Securities Act with respect to the shares offered hereby. This Reoffer Prospectus does not contain all of the information set forth in the registration statement, as permitted by the rules and regulations of the Commission. For further information with respect to Axonyx Inc. and the shares offered, reference is made to the registration statement. Statements contained in this Reoffer Prospectus or in any document incorporated by reference regarding the contents of any agreement or other document are not necessarily complete and are qualified in their entirety by reference to that agreement or document. The registration statement may be inspected without charge at the office of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549, and copies may be obtained from the Commission at prescribed rates.

Axonyx Inc. will furnish to each person to whom this Reoffer Prospectus is delivered, upon written request, a copy of any or all of the documents referred to by reference, other than exhibits to such documents unless such exhibits are specifically incorporated by reference. Requests should be addressed to: Axonyx Inc.

500 Seventh Ave., 10th Floor
New York, New York 10018
Attention: S. Colin Neill, Chief Financial Officer
Telephone (212) 645-7704.

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## INCORPORATION OF DOCUMENTS BY REFERENCE

Axonyx Inc. hereby incorporates by reference into this Reoffer Prospectus the following documents previously filed with the Securities and Exchange Commission ("SEC"):

- 1. The Quarterly Reports on Form 10-Q for the quarter ended March 31, 2004, filed with the SEC on May 14, 2004, and for the quarter ended June 30, 2004, filed with the SEC on August 11, 2004;
- 2. The Annual Report on Form 10-K for the year ended December 31, 2003, filed with the SEC on March 30, 2004;
- 3. The Current Reports on Form 8-K filed with the SEC on January 12, 2004, January 20, 2004 (as amended on Form 8-K/A filed with the SEC on March 30, 2004), May 5, 2004, June 4, 2004, June 4, 2004 and June 10, 2004; and
- 4. The description of our common stock set forth in the Amendment No. 1, Registration Statement on Form 10-SB, filed with the SEC on August 10, 1999.

All reports and definitive proxy or information statements filed pursuant to Section 13(a), 13(c), 14 and 15(d) of the Securities Exchange Act of 1934 (the "1934 Act"), after the date of this Reoffer Prospectus and prior to the termination of the offering of the securities registered shall be deemed to be incorporated by reference into this Reoffer Prospectus and to be a part hereof from the date of filing of such documents. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Reoffer Prospectus to the extent that a statement contained herein or in any subsequently filed document which also is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Reoffer Prospectus.

## THE COMPANY

We are a biopharmaceutical company, specialized in central nervous system (CNS) neurodegenerative diseases, engaged in the business of acquiring the patent rights to clinical stage compounds, compounds with strong proof of concept data and compounds ready for proof of concept validation with convincing scientific rationale. We further develop and add value to these compounds and then seek to out-license or partner them when we believe it business prudent. We have acquired worldwide exclusive patent rights to three main classes of therapeutic compounds designed for the treatment of Alzheimer's disease (AD), 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

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are thought to be caused by an infectious form of a protein called a prion. Prions, unlike viruses, bacteria and fungi, have no DNA and consist only of protein. Such diseases include Creutzfeldt Jakob Disease, new variant in humans, Bovine Spongiform Encephalopathy (BSE or Mad Cow Disease) in cows, and Scrapies disease in sheep. We have licensed these patent rights separately from New York University and from the National Institutes of Health/National Institute on Aging (via a sublicense). We also have co-inventorship rights to a patent application regarding a therapeutic compound named Posiphen designed for the treatment of Alzheimer's disease.

We out-source all of our pre-clinical and clinical research and development, utilizing contract research organizations, or CROs, and sponsored research arrangements. We have contracted with several CROs to undertake the pre-clinical and clinical development of Phenserine. We have entered into a License Agreement with Applied Research Systems ARS Holding N.V. (ARS), a subsidiary of Serono International, S.A. (Serono), a Swiss biopharmaceutical company, under which ARS has the rights to conduct research and development on certain of our licensed technologies. We received an up-front fee and a milestone payment, and may receive future milestone payments and royalties, under the License Agreement. We are currently renegotiating our arrangement with Serono as discussed in note (7) to the condensed consolidated financial statements contained in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed with the SEC on August 11, 2004, and incorporated by reference herein. We do not currently maintain any laboratory or research premises.

Our current business strategy is to concentrate our financial resources primarily on the further development of our licensed compounds, and in particular, Phenserine, an inhibitor of acetylcholinesterase, that is our lead drug candidate for the treatment of AD. Acetylcholinesterase is an enzyme in the synapse that degrades the neurotransmitter acetylcholine in the brain and other tissues of the body. Acetylcholine is a chemical substance that sends signals between nerve cells, called neurotransmission, and is therefore called a neurotransmitter. Neurotransmitters are secreted by neurons, or nerve cells, into the space between neurons called the synapse. Acetylcholine is a primary neurotransmitter in the brain, and is associated with memory and cognition.

In early June 2003, we initiated a Phase IIb clinical trial designed to evaluate the effects of Phenserine on the levels of beta-amyloid precursor protein and beta amyloid in the plasma and cerebrospinal fluid of AD patients. The beta amyloid protein is one of more than a dozen types of amyloid proteins found in the body. Beta amyloid is derived from the beta-amyloid precursor protein normally present in the brain of healthy individuals in small quantities. Beta-amyloid, derived from the beta-amyloid precursor protein, is over-produced in AD and Down's Syndrome. In AD, the beta-amyloid protein undergoes a conformational change, aggregates and is deposited as insoluble fibrils in amyloid plaques in the brain. The beta-amyloid precursor protein is present in the cell wall of numerous cells within the body including nerve cells of the brain. Beta-amyloid protein is derived from this larger protein. In late June 2003 we also initiated a Phase III potentially pivotal clinical trial to further examine the safety and efficacy of Phenserine

on AD patients. In June 2004 we completed enrollment in the 1st Phase III trial and initiated a 2nd Phase III trial with 450 patients.

In addition to the Phenserine clinical program, we are sponsoring pre-clinical research relating to an assay method for screening drug candidates for Alzheimer's disease. Pursuant to a sublicense agreement with ARS, ARS has the rights to undertake research and development concerning the development of (1) compounds called Amyloid Inhibitory Peptides ("AIPs"), which may prevent and reverse the formation of amyloid plaques in AD, and (2) a pharmaceutical compound for prion-related diseases. In Alzheimer's disease the conversion of beta-amyloid protein into insoluble beta-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 amyloid plaques that appear to be a cause of the death of neurons in the brain. The AIPs, also referred to as beta-sheet breaker peptides, have been designed to block the aggregation of beta-amyloid in a competitive manner by binding to the beta-sheet form of the amyloid protein, thus preventing the formation of amyloid plaques in the brain. The beta-sheet breaker peptide is a molecule composed of naturally occurring amino acids, the building blocks of proteins, which is designed to bind to and prevent the conversion of the normal form of protein to the misshapen form that is found in amyloid plaques.

We have initiated the preclinical development of Posiphen, a compound that appears to decrease the formation of the beta-amyloid precursor protein with potential applications in the treatment of AD, and given sufficient financial resources, we may, in the future, sponsor further pre-clinical development of Tolserine, another acetylcholinesterase inhibitor and one of our butyrylcholinesterase inhibitors. Acetylcholinesterase inhibitors are drugs designed to selectively inhibit acetylcholinesterase. Butyrylcholinesterase is an enzyme that is normally found widely in the body. Its function in the central nervous system remains to be fully understood. Amongst other roles, it degrades acetylcholine, a primary neurotransmitter in the brain. Butyrylcholinesterase is found in high concentration in the plaques taken from individuals who have died from AD. This enzyme also functions to degrade a number of drugs and natural products and is involved in their elimination from the body.

The AD targeted approaches include:

- Phenserine, an inhibitor of acetylcholinesterase and the beta-amyloid precursor protein, our lead drug candidate, and Tolserine, another follow-on acetylcholinesterase inhibitor;
- 2) a butyrylcholinesterase inhibitor which will be chosen from a series of selectively acting compounds;
- Posiphen, a compound that decreases the formation of beta-amyloid precursor protein;

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4) through our sublicense with ARS, a subsidiary of Serono, which is described in greater detail below, compounds called Amyloid Inhibitory Peptides (AIPs) which may prevent and reverse the formation of amyloid plaques in AD.

On May 2, 2000, ARS, a subsidiary of Serono, exercised its right to license certain of our patent rights under the Development Agreement and Right to License signed with us in May of 1999. Under that agreement, ARS paid us a \$250,000 non-refundable fee for the right to license. Pursuant to the resulting License Agreement, which became effective on September 15, 2000, ARS acquired

exclusive worldwide patent rights to our AIP and Prion Inhibitory Peptide technologies, called the Licensed Products. In conjunction with the signing of the License Agreement with ARS, we generated \$1.5 million of revenue in the form of an up-front license fee. We received a milestone payment of \$1 million in April 2003 from ARS in relation to the initiation of a Phase I clinical trial with a licensed AIP compound. While we may generate additional revenues from ARS if they reach certain development milestones concerning the licensed compounds or other products and related intellectual property, we are currently renegotiating the terms of the Serono agreement as described in note (7) to the condensed consolidated financial statements contained in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed with the SEC on August 11, 2004, and incorporated by reference herein.

We are also funding research at Monash University in Australia relating to the development of an assay method for the rapid screening of potential drug candidates for the treatment of Alzheimer's disease. We have signed a Research Agreement with the principal researcher, David Henry Small, Ph.D., to fund this research over a three-year period ending in May 2005. It is anticipated that the Axonyx rights to the assay may be transferred to the Serono-Axonyx public entity as described in note (7) to the condensed consolidated financial statements contained in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed with the SEC on August 11, 2004, and incorporated by reference herein.

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

We have incurred negative cash flows from operations since the inception of the Company in 1997. Our net losses for the three fiscal years ended 2001, 2002, and 2003 were \$8,144,000, \$6,256,000 and \$8,106,000 respectively. As of June 30, 2004, we had an accumulated deficit of \$46,851,000 and our operating losses are continuing. Except for OXIS, we have no products available for sale and we do not expect to have any products commercially available for several years, if at all.

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On January 15, 2004, we entered into separate agreements with several holders of the common stock of OXIS International, Inc. (OTC: OXIS.OB) ("OXIS") to acquire approximately 53% of the outstanding voting stock of OXIS. OXIS is a biopharmaceutical/diagnostic company engaged in the development of research diagnostics, nutraceuticals and therapeutics in the field of oxidative stress. We acquired an aggregate of approximately 14 million shares of OXIS stock, in consideration for our issuance of an aggregate of approximately 1.6 million shares of our unregistered common stock. We filed a registration statement on Form S-3 to register the shares of Axonyx common stock that were issued in the exchange, which was declared effective by the SEC in May 2004. Marvin S. Hausman, M.D., our Chairman and Chief Executive Officer, owns 1,161,532 shares of OXIS common stock, representing approximately 4% of OXIS' voting stock. Dr. Hausman's shares of OXIS common stock were not subject to this exchange for our common stock.

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

#### RECENT CHANGES

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

On January 15, 2004, as indicated above, we entered into agreements to acquire approximately 53% of the outstanding voting stock of OXIS. Our Chairman and Chief Executive Officer owns 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. In June 2004, we loaned OXIS \$1.2 million, which will be due and payable in one year or until a qualified financing occurs (whichever is earlier). Interest on this loan accrues at 7% per annum and is payable quarterly. This loan is partially secured by certain assets of OXIS. The loan, in the form of a one-year secured note, will be used to continue the advancement of OXIS' oxidative stress programs and other working capital purposes.

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

In July 2004, we signed a non-binding Memorandum of Understanding (MOU) with Serono International, S.A. (NYSE: SRA) for the research and joint development of

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therapeutic compounds and diagnostic technologies in the field of protein mis-folding disorders such as Parkinson's Disease, Down's Syndrome, Diabetic disorders, Lou Gehrig's Disease, Alzheimer's Disease, Transmissible Spongioform Encephalopathies (TSE's) i.e. Mad Cow Disease (BSE) and Creutzfeldt Jakob Disease new variant (CJDnv).

The MOU proposes that Serono and Axonyx each will transfer certain technologies and proprietary rights to a public entity they will jointly acquire, including technologies previously licensed by us to Serono, as well as additional related intellectual property and expertise subsequently developed by Serono. In addition to contributing specifically enumerated technologies to the new venture, Axonyx will invest \$5 million and own no less than approximately 70% of the newly formed company. The parties anticipate that some time after its formation and following mutual due diligence, the new venture will then separately raise additional capital in the public markets to fund its research and development activities. The ultimate objective is to form a company that will specialize in the development of therapeutic compounds for the diagnosis and treatment of protein mis-folding disorders. Our company will have a majority of the voting stock of the new venture and initially will designate all of its directors.

Under the terms of the MOU, the Chief Operating Officer of the new venture

will be Dr. Silvano Fumero, formerly the head of research and development at Serono, and the parties anticipate that the new venture will enter into a collaborative research agreement with Creabilis Therapeutics srl, a private company controlled by Dr. Fumero. The Chief Scientific Officer will be Dr. Claudio Soto, who was responsible for the initial discovery and development of the key technology that will be contributed to the joint venture.

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

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

Following the signing of the MOU, the parties have been negotiating the terms of definitive agreements. Although there is no assurance that a closing will occur, the parties hope to be able to finalize documents and consummate the transactions in the near future.

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#### RISK FACTORS

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 Reoffer Prospectus contains, in addition to historical information, forward-looking statements, including statements about future plans, objectives, and intentions, that involve risks and uncertainties. Our actual results may differ materially from the results discussed in the forward-looking statements. Factors that might cause or contribute to these differences include those discussed below and elsewhere in this Reoffer Prospectus.

## Risks Related to Our Business

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

We have a limited operating history upon which investors may base an evaluation of our likely future performance. Since we began operations in 1997 we have been engaged in developing our research programs, recruiting outside directors, employees and key consultants, and consummating patent licensing agreements. To date, we have not had any in-house laboratory facilities in which to conduct any research and will not have any operational laboratories of our own in the near future. We have had only limited revenue from license fees in the amount of \$2.75 million to date. As of June 30, 2004, we had an accumulated deficit of \$46,851,000 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 Phenserineand any products developed by OXIS, all of our drug candidates are at an early stage of development and all of our drug candidates will require expensive and lengthy testing and regulatory clearances.

None of our drug candidates have been approved by regulatory authorities. We have no products available for sale and we do not expect to have any products commercially available for several years, if at all. There are many reasons that we may fail in our efforts to develop our drug candidates, including that:

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

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

We cannot assure you that our sponsored research will lead to the successful development of any therapeutic agents. If any potential products are identified, they will require significant additional research, development, preclinical 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.

To obtain regulatory approvals needed for the sale of our drug candidates, we must demonstrate through preclinical testing and clinical trials that each drug candidate is both safe and effective for the human population that it was intended to treat. The clinical trial process is complex and the regulatory environment varies widely from country to country. Positive results from preclinical testing and early clinical trials do not ensure positive results in the pivotal human clinical trials. Many companies in our industry have suffered significant setbacks in pivotal clinical trials, even after promising results in earlier trials. The results from our trials, including our current Phase IIB or Phase III Phenserine trials, may show that our drug candidates produce undesirable side effects in humans or that our drug candidates are not safe or effective. 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. 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:

- o the size of the patient population,
- o the nature of the protocol (i.e., how the drug is given, and the size and frequency of the dose),

- o the proximity of patients to clinical sites, and
- o the eligibility criteria for the clinical trial (i.e., age group, level or symptoms, etc.).

Delays in patient enrollment 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.

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

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

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

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

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

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

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

Certain pass through provisions from the License Agreement between CURE, LLC and the PHS are contained in our License Agreement with CURE, LLC. These pass through provisions are binding on us as if we were a party to the License Agreement with the PHS. Those provisions cover certain reserved government rights to the licensed patents, obligations to meet certain benchmarks and perform a commercial development plan, manufacturing restrictions, as well as indemnification, termination and modification of rights. PHS reserves on behalf of the U.S. government or any foreign government or international organization pursuant to any existing or future treaty or agreement with the U.S. government an irrevocable, nonexclusive, nontransferable, royalty free license for the practice of all inventions licensed pursuant to the License Agreement between CURE and PHS for research or other purposes. After making the first commercial sale of licensed products until expiration of the agreement, we must use our reasonable best efforts to make the licensed products and processes reasonably accessible to the U.S. public. PHS reserves the right to terminate or modify the License Agreement if it is determined that such action is necessary to meet requirements for public use specified by federal regulations. We are also obligated, under these pass through provisions, to manufacture licensed products substantially in the U.S., unless a written waiver is obtained in advance from the PHS. We undertook to develop and commercialize the licensed products covered by the patents pursuant to a commercial development plan contained in a pass through provision from the CURE-PHS license agreement. If we fail to cure non-compliance with the commercial development plan after notice from CURE within a reasonable period of time, we could be in material breach of the agreement. We have not, as of the date this Reoffer Prospectus, received notice of default of any of our obligations from CURE, LLC, or the PHS.

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

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future revenues under this sublicense agreement or under any other future sublicensing agreements concerning our patent rights to other drug candidates, if any.

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

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

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

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

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

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

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

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

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

o the progress and magnitude of our drug development programs,

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- o the scope and results of preclinical testing and clinical trials,
- o the cost, timing and outcome of regulatory reviews,
- o 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,
- o the costs of acquiring any technologies or additional drug candidates,
- o the rate of technological advances,
- o the commercial potential of our drug candidates,
- o  $\,$  the magnitude of our administrative and legal expenses, including office rent, and  $\,$

o 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 September 2003, we have raised approximately \$95 million through financings and an additional \$5.1 million through the cash exercise of various warrants 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, most of whom do not have employment contracts.

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 our Chief Executive Officer and Chairman, Marvin S. Hausman, M.D. and/or Gosse B. Bruinsma, M.D., our President and Chief Operating Officer, and/or S. Colin Neill, our Chief Financial Officer and Treasurer, would be detrimental to us. We do not currently have employment agreements with our officers, except Gosse B. Bruinsma, M.D. (other than change of control agreements, as described in our Annual Report on Form 10-K for 2003). We do not have employment agreements with key

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scientific personnel who are doing research at the National Institute of Aging related, in some cases, to pharmaceutical compounds licensed via a sublicense to Axonyx, and have no assurance that such personnel will continue to be involved with such research. We do not carry key man insurance on any of our personnel.

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

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

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

We have licensed rights to certain patented and patent pending proprietary technology from NYU and CURE, LLC to which we are obligated to pay royalties if we or our sublicensees develop products based upon the licensed technology. Because of the substantial length of time, effort and expense associated with bringing new products through development and regulatory approval to the

marketplace, the pharmaceutical industry places considerable importance on patent and trade secret protection for new technologies, products and processes. We have interests in eight patents issued in the United States. We obtained patent rights in six of those patents from our licensors at New York University and CURE, LLC. We sublicensed the rights to two of those six patents to by Applied Research Systems ARS Holding N.V., a subsidiary of Serono International, S.A. We have also filed two patent applications, one in conjunction with the NIH and two co-inventor scientists, that have become issued patents in the United States. In addition to the eight issued patents, we have filed four patent applications in the United States. We have co-ownership patent rights to two of these patent applications. We have ownership rights to one of the patent applications pursuant to assignment by the inventors and we have sublicensed the fourth patent application to ARS. We are obligated to pay the filing, prosecution and maintenance expenses with regard to all of these patents and patent applications. We and our licensors have filed patent applications in other countries, and we may seek additional patents in the future. Our patent position, like that of many pharmaceutical companies, is uncertain and involves complex legal and factual questions for which important legal principles are unresolved. We may not develop or obtain rights to products or processes that are patentable. Even if we do obtain patents, they may not adequately protect the technology we own or have in-licensed. In addition, others may challenge, seek to invalidate, infringe or circumvent any patents we own or in-license, and rights we receive under

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those patents may not provide competitive advantages to us. Further, the manufacture, use or sale of our products or processes, if any, may infringe the patent rights of others.

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

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

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

In the United States, the first to invent a technology is entitled to

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

While we have not received notification of potential infringement of patents held by third parties, with respect to any of our drug candidates, litigation, patent opposition and adversarial proceedings could result in substantial costs to us. Litigation and/or proceedings could be necessary or may be initiated to enforce any patents we own or in-license, or to determine the scope, validity and enforceability of other parties' proprietary

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rights and the priority of an invention. The outcome of any of these types of proceedings could significantly affect our drug candidates and technology. United States patents carry a presumption of validity and generally can be invalidated only through clear and convincing evidence.

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

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

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

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

Licensing product candidates from other companies, universities or individuals does not always prevent them from developing non-identical but competitive products for their own commercial purposes, nor from pursuing patent protection in areas that are competitive with us. The partners who created these technologies are sophisticated scientists and business people who may continue to do research and development and seek patent protection in the same areas that led to the discovery of the product candidates that they licensed to us. The development and commercialization of successful new drugs from our research program is likely to attract additional research by our licensors in addition to other investigators who have experience in developing products for the memory and cognition market. By virtue of the previous research that

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led to the discovery of the drugs or product candidates that they licensed to us, these companies, universities, or individuals may be able to develop and market competitive products in less time than might be required to develop a product with which they have no prior experience.

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

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

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

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

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

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

Bisnorcymserine, or Posiphen. A decision not to commercialize these drug candidates could adversely affect our business.

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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, 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.

We are significantly controlled by our management.

Our executive officers comprise two of the six members of our Board of Directors. As a result, our management has the ability to exercise influence over significant matters. This high level of influence may have a significant effect in delaying, deferring or preventing a change of control of our company.

Risks Related to Our Industry

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

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

Our business strategy is based in part upon inhibition of amyloid conformational change and amyloid precursor protein processing and the application of these new and unproven technologies to the development of biopharmaceutical products for the treatment of Alzheimer's disease and other neurological disorders. We cannot assure you

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

There are many companies, both public and private, including well-known pharmaceutical companies, engaged in developing synthetic pharmaceutical and biotechnological products for human therapeutic applications in the Alzheimer's disease area. Our major competitors are currently the pharmaceutical companies that are marketing the acetylcholinesterase inhibitors for the treatment of Alzheimer's disease. The market for such is dominated primarily by Pfizer with its drug Aricept. The other significant drugs are Exelon marketed by Novartis and Reminyl marketed by Jansen Pharmaceuticals. These are large pharmaceutical companies with far ranging capabilities to market their drugs and to develop follow on drug products. Although our major potential drug Phenserine is currently in Phase III clinical trials, there can be no quarantees that we will obtain regulatory approval for Phenserine and such approval, even if obtained, may be years away. In addition we do not have the capability or the resources of marketing a drug and will have to enter into a collaborative relationship with a larger pharmaceutical company in order to market Phenserine. As Phenserine is also an acetylcholinesterase inhibitor, like the currently marketed drugs, unless the data from future Phenserine clinical trials 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 preclinical 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

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investment in these fields. Other companies are engaged in research and product development based on amyloidogenesis and acetylcholinesterase inhibition.

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

Accordingly, our competitors may commercialize products more rapidly or effectively than we do, which could hurt our competitive position.

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

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

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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 quidelines 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:

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

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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 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.

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.

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.

Sales of our common stock may cause our stock price to decline.

The sale of our shares by our selling securityholders from time to time, or even the potential of such sale, may have an adverse effect on the price of our common stock. The sales of our shares in the future may also have an adverse effect on the price of our common stock. There are currently approximately 4.0 million shares of our common

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stock outstanding that are "restricted securities" as that term is defined by Rule 144 under the Securities Act of 1933. Such shares will be eligible for public sale only if registered under the Securities Act or if sold in accordance with Rule 144. We have registered and are in the process of registering additional shares for selling shareholders. Under Rule 144, a person who has held restricted securities for a period of one year may sell a limited number of shares to the public in ordinary brokerage transactions. The timing and amount of sales of common stock that are currently restricted securities could have a depressive effect on the future market price of our common stock.

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

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

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

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

- o announcements of the results of clinical trials by us or our competitors,
- o developments with respect to patents or proprietary rights,
- o announcements of technological innovations by us or our competitors,

- o announcements of new products or new contracts by us or our competitors,
- o actual or anticipated variations in our operating results due to the level of development expenses and other factors,
- o changes in financial estimates by securities analysts and whether our earnings meet or exceed such estimates,
- o conditions and trends in the pharmaceutical and other industries,
- o new accounting standards,
- o general economic, political and market conditions and other factors, and

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o the occurrence of any of the risks described in these "Risk Factors."

In the past two years, the price range of the closing prices for our common stock has been between a high of \$8.75 and a low of \$0.51. In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against those companies. If we face such litigation in the future, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

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 August 27, 2004, we had outstanding options to purchase an aggregate of 4,943,319 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 4,381,380 shares of our common stock under the option plans.

In addition, we have granted options to purchase an aggregate of 355,000 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  $10,465,193 \ \mathrm{shares}$  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.

#### USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares by the selling securityholders. We may, in the future, receive proceeds from the exercise of options  $\frac{1}{2}$ 

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described in this Reoffer Prospectus, but only in an amount equal to the exercise price of the option multiplied by the number of options exercised. We will use any such proceeds for working capital and general corporate purposes.

## SELLING SECURITYHOLDERS

The selling securityholders that may offer shares of our common stock pursuant to this Reoffer Prospectus are persons who were granted or may be granted options under our option plans. All of the shares of common stock offered pursuant to this Reoffer Prospectus are being offered for the account of the selling securityholders.

The term "selling securityholder" includes (i) each person that is identified in the table below and (ii) any transferee, donee, pledgee or other successor of any person named in the table that acquires any of the shares covered by this Reoffer Prospectus in a transaction exempt from the registration requirements of the Securities Act of 1933 and that is identified in a supplement to this Reoffer Prospectus.

Except as otherwise specified in the table below, after the offering, assuming all shares offered hereby are sold, none of the selling securityholders will own one percent or more of the outstanding shares of our common stock.

Except as otherwise specified in the footnotes to the table below, during the last three years, no selling securityholder has been an officer, director or affiliate of our company, nor has any selling securityholder had any material relationship with our company during that period.

The shares being offered hereby are being registered to permit public secondary trading, and the selling securityholders are under no obligation to sell all or any portion of their shares of common stock included in this Reoffer Prospectus. The information contained in the following table is derived from our books and records, as well as from our transfer agent. The following table assumes the sale of all shares included in this Reoffer Prospectus.

The table below identifies each selling securityholder and indicates the number of shares issuable or that were issued to such selling securityholder upon exercise of the options that were granted to such selling securityhoder under the option plans. Each selling securityholder may use this Reoffer Prospectus to sell the shares beneficially owned by him.

We will, from time to time, supplement this Reoffer Prospectus in order to reflect option grants under the plan to grantees who are officers and/or directors and to name them as selling securityholders.

Name of Selling Securityholder	Number of Shares owned prior to offering (1)	Number of Shares Offered Hereby	Number of Shares Owned after offerin
4P Management Partners L.P. (2)	25,000	25,000	0
Alexander Angerman (2)	112,100	25,000	87,100
Richard Salvador (3)	100,000	50,000	50,000

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- (1) Represents shares beneficially owned by the named selling securityholder, including shares that such selling securityholder has the right to acquire within 60 days of the date of this Reoffer Prospectus. Unless otherwise noted, all persons referred to above have sole voting and investment power over the securities they beneficially own.
- (2) The selling securityholder is a consultant to the Company.
- (3) The selling securityholder was a consultant to the Company until February 2003.

#### PLAN OF DISTRIBUTION

The selling securityholders are offering the shares of common stock for their own account, and not for the account of Axonyx Inc. We will not receive any proceeds from the sale of the common stock by the selling securityholders. However, we will receive the proceeds from any exercise of stock options granted or to be granted under the plans.

From time to time, for their own accounts, selling securityholders may sell the common stock offered hereby, subject to certain restrictions contained in the underlying documents granting the options to purchase such shares, directly to purchasers or through agents, brokers, dealers or underwriters. Such agents, brokers, dealers or underwriters may receive concessions or commissions that exceed customary commissions from the selling securityholders or purchasers of the shares. Sales of the shares may be made in one or more transactions through the Nasdaq Small Cap Market, in the over-the-counter market, in privately negotiated transactions or otherwise. Sales may be made at the market price at the time of sale, a price related to the market price or a negotiated price.

Any brokers, dealers or agents that participate in the distribution of the shares may be deemed to be underwriters and any commissions received by them and any profit on the resale of such shares positioned by them might be deemed to be underwriting discounts and commissions under the Securities Act of 1933.

To the extent required, we will use our best efforts to file, during any period in which offers or sales are being made, one or more supplements to this Reoffer Prospectus to describe any material information with respect to the plan of distribution not

<sup>\*</sup> Less than 1%

previously disclosed in this Reoffer Prospectus or any material change to the information in this Reoffer Prospectus.

#### EXPERTS

Eisner LLP, a registered independent public accounting firm, has audited our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2003, as set forth in their report, which is incorporated by reference in this Reoffer Prospectus. Our financial statements are incorporated by reference in reliance on such report of Eisner LLP, given on their authority as experts in accounting and auditing.

#### LEGAL MATTERS

The validity of the shares offered hereby were passed upon for us by Ehrenreich Eilenberg & Krause LLP, 11 East 44th Street, 17th Floor, New York, NY 10017.

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#### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, New York, on the 30th day of August, 2004.

AXONYX INC.

By: /s/ Marvin S. Hausman

Marvin S. Hausman, M.D.

Chief Executive Officer, Chairman

We, the undersigned, hereby severally constitute and appoint Marvin S. Hausman, M.D. and S. Colin Neill and each of them individually as our true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for us and in our name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as we might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in their respective capacities and on the dates indicated:

Signature Title

/s/ Marvin S. Hausman	Chief Executive Officer, Chairman and Director (Principal Executive Officer)	August 30, 2004
Marvin S. Hausman, M.D.		
/s/ Gosse B. Bruinsma	Chief Operating Officer, President and Director	August 30, 2004
Gosse B. Bruinsma, M.D.	and birector	
/s/ S. Colin Neill	Chief Financial Officer, Treasurer	August 30, 2004
S. Colin Neill	and Secretary (Principal Financial and Accounting Officer)	
	Director	
Louis G. Cornacchia		
/s/ Steven H. Ferris	Director	August 30, 2004
Steven H. Ferris, Ph.D		
/s/ Ralph Snyderman	Director	August 30, 2004
Ralph Snyderman, M.D.		
	Director	
Gerard J. Vlak, Ph.D.		