AXONYX INC
Form 424B3
February 13, 2004

Pursuant to Rule 424(b)(3)
File Number: 333-112489

PROSPECTUS

AXONYX INC.

12,641,740 shares of common stock

This prospectus covers the offer and sale of up to 12,641,740 shares of common stock of Axonyx Inc. from time to time by certain selling security holders named in this prospectus.

The shares being offered by the selling security holders include:

- 9,650,183 shares of our issued and outstanding common stock currently held by the selling security holders; and

- 2,991,557 shares of common stock issuable upon exercise of outstanding warrants to purchase common stock.

The prices at which the selling security holders may sell these shares will be determined by the prevailing market price for shares of our common stock or in negotiated transactions. We will not receive any of the proceeds from the sale of the shares of common stock. However, we will receive the exercise price of the warrants underlying some of the common stock upon exercise by the selling security holders, to the extent the warrants are exercised for cash.

Our common stock is traded on the Nasdaq SmallCap Market under the symbol "AXYX". On February 13, 2004, the last reported sale price for our common stock was $7.05 per share.

The common stock offered involves a high degree of risk. See "Risk Factors" commencing on page 7 for a discussion of some important risks you should consider before buying any shares of common stock.

Neither the Securities and Exchange Commission, nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 13, 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 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 prospectus, nor any sale made under this prospectus shall, under any circumstances, imply that the information in this prospectus is correct as of any date after the date of this prospectus.

WHERE YOU CAN FIND MORE INFORMATION

We file reports, proxy statements and other information with the Securities and Exchange Commission, or SEC. You may read and copy any document we file at the SEC's public reference rooms in Washington, D.C., New York, New York and Chicago, Illinois. The SEC's public reference room in Washington, D.C. is located at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our SEC filings are also available to the public on the SEC's website at http://www.sec.gov.

The SEC allows us to "incorporate by reference" the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and later information filed with the SEC will update and supersede this information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Section 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 until the offering is completed.

1. Our Annual Report on Form 10-K for the year ended December 31, 2002 (file no. 000-25571);

2. Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2003, June 30, 2003 and September 30, 2003 (file no. 000-25571);

3. Our Current Reports on Form 8-K dated April 7, 2003, June 18, 2003, September 16, 2003, January 12, 2004 and January 20, 2004; and

4. The description of our common stock set forth in our Amendment No. 1 to Registration Statement on Form 10-SB, filed with the SEC on August 10, 1999.

The reports and other documents that we file under the Exchange Act after the date of this prospectus and before all of the shares under it have been sold will be incorporated by reference into this prospectus and will update and supersede the information in this prospectus.

This prospectus does not contain all of the information set forth in the registration statement and the exhibits thereto. Descriptions of any contract or other document referred to in this prospectus are not necessarily complete, and in each instance reference is made to the copy of the contract or other document

filed as an exhibit to the registration statement for a more complete description of the matter involved, each statement being qualified in its entirety by such reference. At your written or telephonic request, we will provide you, without charge, a copy of any of the information that is incorporated by reference herein (excluding exhibits to the information that is incorporated by reference unless the exhibits are themselves specifically incorporated by reference). Direct your request to us by writing or telephoning us at:

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

THE COMPANY

We are engaged in the business of acquiring and developing novel post-discovery central nervous system drug candidates, primarily in areas of memory and cognition. We acquire patent rights to central nervous system pharmaceutical compounds we believe may have significant potential market impact and work to advance the compounds through clinical development towards regulatory approval. 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 are thought to be caused by an infectious 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 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 therapeutic compound named Posiphen designed for the treatment of Alzheimer's disease.

We out-source all of our preclinical 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 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 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 do not currently maintain any laboratory or research premises.

Our current business strategy is to concentrate our financial resources primarily on the further clinical development of 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

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 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, or 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, that is designed to bind to and prevent the conversion of the normal form of protein to the misshapen form that forms amyloid plaques.

Given sufficient financial resources, we may, in the future, sponsor further pre-clinical development of Tolserine, another acetylcholinesterase inhibitor, some of our butyrylcholinesterase inhibitors, and initiate pre-clinical development of Posiphen, a compound that appears to decrease the formation of the beta-amyloid precursor protein with potential applications in the treatment of AD. 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:

(1) Phenserine, an inhibitor of acetylcholinesterase and the beta-amyloid 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;

(3) Posiphen, a compound that decreases the formation of beta-amyloid precursor protein;

(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. We may generate additional revenues from ARS if they reach certain development milestones concerning the licensed compounds or other products and related intellectual property, although additional milestone payments did not occur in fiscal year 2003. Axonyx could receive milestone payments from ARS in an aggregate amount of $13 million if the Licensed Product involved is a patented product covered by the sub-licensed patents and patent applications and it achieves certain developmental milestones up through health registration approval. The amount of aggregate milestone payments through health registration approval would be $7 million if the Licensed Product involved was developed by Serono during the one year term of the Development Agreement we entered into with ARS in May 1999. We cannot assure you that licensed compounds or products will reach any particular stage of development requiring a milestone payment, that licensed compounds or products will ever reach the market and give rise to royalty payments, or that additional revenues from patent licensing will be generated.

Through our sublicense with ARS, Serono has the right to conduct research and development work on compounds called Prion Inhibitory Peptides designed for the diagnosis and treatment of prion diseases such as Bovine Spongiform Encephalopathy (also known as Mad Cow Disease) and the human form of the disease, Creutzfeldt Jakob Disease, new variant.

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

In December 2000 Axonyx incorporated Axonyx Europe BV, a wholly owned subsidiary, in the Netherlands. Gosse Bruinsma, M.D., currently the President and Chief Operating Officer of Axonyx, was appointed the President of Axonyx Europe BV. Axonyx Europe explores out-licensing opportunities for Axonyx's licensed technologies in Europe and other areas outside the United States, facilitates communication with Axonyx's European shareholders, and is assisting in organizing and administering our planned clinical research in Europe and future potential pre-clinical and clinical studies there. Axonyx has established a Scientific Advisory Board to assist

in clinical protocol design as well as the identification of novel central nervous system technology and products for potential licensing.

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 2000, 2001, and 2002 were $4,870,000, $8,144,000 and $6,256,000, respectively, and $4,624,000 for the nine months ending September 30, 2003. As of September 30, 2003, we had an accumulated deficit of $30,246,000 and our operating losses are continuing. We have no products available for sale and we do not expect to have any products commercially available for several years, if at all.

On January 20, 2004, we announced that we entered into agreements to acquire approximately 53% of the outstanding voting stock of OXIS International, Inc. (OTC: OXIS.OB). OXIS is a biopharmaceutical/diagnostic company engaged in the development of research diagnostics, nutraceuticals and therapeutics in the field of oxidative stress. Under the terms of separate agreements entered into with several holders of OXIS common stock, we will be acquiring 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 have agreed to register our shares of common stock being issued in the exchange in the near future. 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 are not subject to this exchange for our common stock.

Axonyx 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.

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

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 September 30, 2003, we had an accumulated deficit of $30,246,000 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.

All of our drug candidates are at an early stage of development and all of our drug candidates will require expensive and lengthy testing and regulatory clearances. None of our drug candidates have been approved by regulatory

authorities. We have no products available for sale and we do not expect to have any products commercially available for several years, if at all. There are many reasons that we may fail in our efforts to develop our drug candidates, including that:

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

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

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

To obtain regulatory approvals needed for the sale of our drug candidates, we must demonstrate through 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:

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

- the proximity of patients to clinical sites, and
- 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.

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

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

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

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

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

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

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

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

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

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

We do not currently have the capability to undertake manufacturing, marketing, or sales of any potential products and we have limited personnel to

oversee out-sourced clinical testing and the regulatory approval process.

We have not invested in manufacturing, marketing or product sales resources. We cannot assure you that we will be able to acquire such resources. It is likely that we will also need to hire additional personnel skilled in the clinical testing and regulatory compliance process if we develop additional product candidates with commercial potential. We have no history of manufacturing or marketing. We cannot assure you that we will successfully manufacture or market any product we may develop, either independently or under manufacturing or marketing arrangements, if any, with other companies. We currently do not have any arrangements with other companies, and we cannot assure you that any arrangements with other companies can be successfully negotiated or that such arrangements will be on commercially reasonable terms. To the extent that we arrange with other companies to

manufacture or market our products, if any, the success of such products may depend on the efforts of those other companies. We do not currently have the capability to conduct clinical testing in-house and do not currently have plans to develop such a capability. We out-source our clinical testing to contract research organizations. We currently have one employee and certain other outside consultants who oversee the contract research organizations involved in clinical testing of our compounds. We cannot assure you that our limited oversight of the contract research organizations will suffice to avoid significant problems with the protocols and conduct of the clinical trials.

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

We have engaged and intend to continue to engage third party contract research organizations, or CROs, and other third parties to help us develop our drug candidates. Although we have designed the clinical trials for our drug candidates, the CROs have conducted all of our clinical trials. As a result, many important aspects of our drug development programs have been and will continue to be outside of our direct control. In addition, the CROs may not perform all of their obligations under arrangements with us. If the CROs do not perform clinical trials in a satisfactory manner or breach their obligations to us, the development and commercialization of any drug candidate may be delayed or precluded. We cannot control the amount and timing of resources these CROs devote to our programs or product candidates. The failure of any of these CROs to comply with any governmental regulations would substantially harm our development and marketing efforts and delay or prevent regulatory approval of our drug candidates. If we are unable to rely on clinical data collected by others, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

We have contracted with or are currently negotiating contracts with several CROs to perform services concerning certain pre-clinical and clinical testing of Phenserine. For example, our subsidiary, Axonyx Europe has contracted with NOTOX Safety and Environmental Research B.V. of Holland to conduct a pre-clinical carcinogenicity study. Other CROs are providing 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:

- the progress and magnitude of our drug development programs,
- the scope and results of preclinical testing and clinical trials,

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

We have incurred negative cash flow from operations since we incorporated and do not expect to generate positive cash flow from our operations for at least the next several years. Although since September 2003, we have raised approximately $75 million through financings and an additional $5 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. We do not have employment agreements with key scientific personnel who are doing research at the National Institute of Aging related, in some cases, to pharmaceutical compounds licensed via a sublicense to Axonyx, and have no assurance that such personnel will continue to be employed in 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 members of our Scientific Advisory Board 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. In addition, it is possible, in certain circumstances, that inventions or processes discovered by them will not become the property of our company but will be the property of their full-time employers.

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

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

States. We have co-ownership patent rights to two of these patent applications. We have ownership rights to one of the patent applications pursuant to assignment by the inventors and we have sublicensed the fourth patent application to ARS. We are obligated to pay the filing, prosecution and maintenance expenses with regard to all of these patents and patent applications. We and our licensors have filed patent applications in other countries, and we may seek additional patents in the future. Our patent position, like that of many pharmaceutical companies, is uncertain and involves complex legal and factual questions for which important legal principles are unresolved. We may not develop or obtain rights to products or processes that are patentable. Even if we do obtain patents, they may not adequately protect the technology we own or have in-licensed. In addition, others may challenge, seek to invalidate, infringe or circumvent any patents we own or in-license, and rights we receive under those patents may not provide competitive advantages to us. Further, the manufacture, use or sale of our products or processes, if any, may infringe the patent rights of others.

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

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

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

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

While we have not received notification of potential infringement of patents held by third parties, with respect to any of our drug candidates,

litigation, patent opposition and adversarial proceedings could result in substantial costs to us. Litigation and/or proceedings could be necessary or may be initiated to enforce any patents we own or in-license, or to determine the scope, validity and enforceability of other parties' proprietary rights and the priority of an invention. The outcome of any of these types of proceedings could significantly affect our drug candidates and technology. United States patents carry a presumption of validity and generally can be invalidated only through clear and convincing evidence.

Under our license agreements with New York University, CURE LLC, ARS, a subsidiary of Serono, and Dr. David Small and co-inventors, we have the right to pursue any actions against third parties for infringement of the patent rights covered by those agreements. Under those arrangements we are obligated to share any recovery over and above that required for reimbursement of our costs and expenses in bringing the infringement

action with our licensors, or in the case of ARS, with our licensee, if ARS joins the suit. Under one of those arrangements, our failure to effect the discontinuance of any infringement after a certain period of time can reduce our royalty income. Under our License Agreement with ARS, if, after the expiration of 90 days of notice of any third party infringement by one party to the other, and we have not obtained discontinuance of such infringement or brought suit against the third party infringer, then the royalty in effect in such country shall be reduced by fifty percent. Such reduced royalty rate shall continue until such infringement ceases.

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

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

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

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

with which they have no prior experience.

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

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

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

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

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

There are significant risks regarding the patent rights surrounding Bisnorcymserine and Phenethylnorcymserine (PENC), two of our potential butyrylcholinesterase inhibitor drug candidates, and for

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

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

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

If our drug candidates do not achieve market acceptance, our business may

never achieve profitability.

Our success will depend on the market acceptance of any products we may develop. The degree of market acceptance will depend upon a number of factors, including the receipt and scope of regulatory approvals, the establishment and demonstration in the medical community of the safety and effectiveness of our products and their potential advantages over existing treatment methods, 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 five 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 that unforeseen problems will not develop with these technologies or applications or that commercially feasible products will ultimately be developed by us.

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

There are many companies, both public and private, including well-known pharmaceutical companies, engaged in developing 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 guarantees 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 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 which could prevent or delay the commercialization of our products, if any.

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

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

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

Health care reform measures and third party reimbursement practices are

uncertain and may adversely impact the commercialization of our products, if any.

The efforts of governments and third party payors to contain or reduce the cost of health care will continue to affect the business and financial condition of drug companies. A number of legislative and regulatory proposals to change the health care system have been proposed in recent years. In addition, an increasing emphasis on managed care in the United States has and will continue to increase pressure on drug pricing. While we cannot predict whether legislative or regulatory proposals will be adopted or what effect those proposals or managed care efforts may have on our business, the announcement and/or adoption of such proposals or efforts could have an adverse effect on our 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 security holders 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 2.7 million shares of our common 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:

- announcements of the results of clinical trials by us or our competitors,
- developments with respect to patents or proprietary rights,
- announcements of technological innovations by us or our competitors,
- announcements of new products or new contracts by us or our competitors,
- actual or anticipated variations in our operating results due to the level of development expenses and other factors,
- changes in financial estimates by securities analysts and whether our earnings meet or exceed such estimates,
- conditions and trends in the pharmaceutical and other industries,
- new accounting standards,

- general economic, political and market conditions and other factors, and
- the occurrence of any of the risks described in these "Risk Factors."

In the past two years, the price range of the closing prices for our common stock has been between a high of $7.74 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 January 31, 2004, we had outstanding options to purchase an aggregate of 4,422,000 shares of our common stock to our employees, officers, directors, and consultants under our 2000 and 1998 Stock Option Plans. We may issue options to purchase an additional 443,000 shares of our common stock under the 2000 Stock Option Plan.

In addition, we have granted options to purchase an aggregate of 375,000 shares of common stock outside of our Stock Option Plans to consultants and others.

There are currently outstanding warrants to purchase an aggregate of 9,581,510 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.

FORWARD-LOOKING STATEMENTS

This 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 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 prospectus

or to conform these statements to actual results unless required by law.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares by the selling security holders, although we will receive the exercise price of the warrants upon exercise by the selling security holders, to the extent that the warrants are exercised for cash. We plan to use the exercise price for working capital. All proceeds from the sale of the shares of common stock covered by this prospectus will go to the selling security holders who offer and sell their shares. In addition, we plan to use for working capital purposes any proceeds we receive from the exercise of warrants to purchase our common stock covered by this prospectus. Assuming all such warrants are exercised through the payment of cash (rather than a net exercise) by the exercising security holders, this may result in up to an additional $21.6 million of proceeds to us.

SELLING SECURITY HOLDERS

On January 8, 2004, we closed a private placement of 9,650,183 shares of common stock and warrants to purchase an additional 2,991,557 shares of common stock. This prospectus covers only the 9,650,183 common shares and the 2,991,557 warrant shares issued in the private placement, which include 482,510 shares of common stock issuable upon the exercise of warrants issued to Rodman & Renshaw Inc. and 96,502 shares of common stock issuable upon the exercise of warrants issued to Punk Ziegel & Company L.P., each as part of placement fees related to the closing of the private placement. We have listed below:

- the name of each selling security holder;
- the number of shares of common stock beneficially owned by the selling security holder as of the date of this prospectus;
- the maximum number of shares of common stock being offered by each of them in this offering; and
- the number of shares of common stock to be owned by the selling security holder after this offering (assuming sale of such maximum number of shares).

After the offering, assuming all shares offered hereby are sold, none of the selling security holders will own one percent or more of the outstanding shares of our common stock, with the exception of Galleon Healthcare Offshore, Ltd. (2.64%) and Smithfield Fiduciary LLC (2.15%).

Except as otherwise noted below, during the last three years no selling security holder has been an officer, director or affiliate of our company, nor has any selling security holder had any material relationship with our company during that period. Each selling security holder represented at the closing of the private placement that they did not have any contract, undertaking, agreement or arrangement with any person to sell, transfer, pledge, hypothecate, grant any option to purchase or otherwise dispose of any of the securities. The selling security holders purchased the shares in the ordinary course of business, to the best of our knowledge.

The shares being offered hereby are being registered to permit public secondary trading, and the selling security holders are under no obligation to sell all or any portion of their shares of common stock included in this 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 prospectus.

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Selling Security Holder	Shares Owned Prior to this Offering	Shares Available Pursuant to this Prospectus	Shares O After Off
Alexandra Global Master Fund Ltd.	603,136	603,136	
Asset Management	48,705	48,705	
Atlas Fund, LLC	625,000	625,000	
BayStar Capital II, LP	361,881	361,881	
Bristol Investment Fund, Ltd	120,627	120,627	
Capital Ventures International	241,255	241,255	
Castle Creek Healthcare Partners LLC	120,627	120,627	
Cohanzick Partners, LP	32,500	32,500	
Cranshire Capital, L.P.	609,219	482,509	126,71
Crescent International Ltd.	100,000	100,000	
DKR Saturn Event Driven Holding Fund Ltd.	248,375	208,375	40,00
DKR Saturn Holding Fund Ltd.	47,625	41,625	6,00
Ehrenkrantz King Nussbaum, Inc.	120,627	120,627	
Elliot Associates, L.P.	144,753	144,753	
Elliot International, L.P.	217,129	217,129	
EGMF, LP	62,500	62,500	
FIPS Health Fund	50,000	50,000	
First New York Securities LLC	106,250	106,250	
FNY Carpediem II L.P.	115,563	115,563	
FNY Carpediem Offshore Ltd.	64,500	64,500	
FNY Carpediem Partners L.P.	88,688	88,688	
Framlington Biotech Fund	137,500	137,500	
Framlington Health Fund	875,000	875,000	
Gabriel Capital, L.P.	88,127	88,127	
Galleon Captains Offshore, Ltd.	301,700	293,750	7,95
Galleon Captains Partners, LP	83,300	81,250	2,05
Galleon Healthcare Offshore, Ltd.	1,810,450	543,750	1,266,70
Galleon Healthcare Partners, LP	239,550	81,250	158,30
Langley Partners, L.P.	417,956	361,881	56,07
Munder Healthcare Fund	262,500	262,500	
North Sound Legacy Fund LLC	16,885	16,885	
North Sound Legacy International Fund LLC	171,290	171,290	
North Sound Legacy International Ltd.	294,335	294,335	
Omicron Master Trust	626,527	402,228	224,29
OTAPE Investments LLC	86,929	24,125	62,80
Portside Growth and Opportunity Fund (1)	768,183	500,000	268,18
Punk, Ziegel & Company (2)	96,502	96,502	
RHP Master Fund, Ltd.	120,627	120,627	
Rodman & Renshaw, Inc. (3)	482,510	482,510	
S.A.C. Capital Associates, LLC	1,222,500	750,000	472,50
Smithfield Fiduciary LLC	1,755,830	723,763	1,032,06
Symmetry Capital Offshore Fund LTD	9,694	9,694	
Symmetry Capital Partners, L.P.	25,513	25,513	
Symmetry Capital Qualified Partners, L.P.	35,045	35,045	
Symmetry Parallax Partners, L.P.	6,044	6,044	
The Riverview Group, LLC	0	363,781	
The Tail Wind Fund Limited	282,310	120,627	161,68
Topaz Partners	603,136	603,136	
Ursus Capital LP	71,125	71,125	
Ursus Offshore Ltd.	49,503	49,503	
VGE III Portfolio Ltd.	595,175	524,875	70,30

Viking Global Equities LP	613,925	537,625	76,30
WSSMF, LP	31,250	31,250	

(1) The Investment Advisor to Portside Growth and Opportunity Fund is Ramius Capital Group, LLC. The Managing Member of Ramius Capital Group, LLC is C4S & Co., the Managing Members of which are Peter Cohen, Morgan Stark and Thomas Strauss. As such, Messrs. Cohen, Stark and Strauss may be deemed beneficial owners of shares issued and issuable to Portside Growth and Opportunity Fund. Messrs. Cohen, Stark and Strauss disclaim beneficial ownership of all of such shares.

(2) Punk Ziegel & Company LLP is a financial advisor to Axonyx Inc. pursuant to a Financial Advisory Agreement dated August 1, 2003. Punk Ziegel acted as a placement agent in the January 8, 2004 private placement and was issued warrants to purchase 96,502 shares of common stock exercisable at $7.25 per share.

(3) Rodman & Renshaw acted as a placement agent to Axonyx in the January 8, 2004 private placement pursuant to an Engagement Letter dated September 5, 2003 and was issued warrants to purchase 482,510 shares of common stock exercisable at $7.25 per share in addition to a cash placement fee.

We have undertaken to maintain the registration current until the earlier of two years from the effective date of the registration statement of which this prospectus is a part, the date when all the shares registered thereunder have been sold or the date when selling security holders may sell under Rule 144(k) in order that sales of shares may be made by the selling security holders. We have agreed to pay for all costs and expenses incident to the issuance, offer, sale and delivery of the shares, including, but not limited to, all expenses and fees of preparing, filing and printing the registration statement and prospectus and related exhibits, amendments and supplements thereto and mailing of such items. We will not pay transfer taxes, selling commissions or underwriting discounts associated with any sales by the selling security holders. We have agreed to indemnify the selling security holders against civil liabilities, including liabilities under the Securities Act of 1933, arising from certain statements, omissions or violations relating to this offering. The selling security holders have agreed to indemnify us and our directors and each officer signing the registration statement against liabilities relating to the information given to us by the selling security holders in writing for inclusion in the registration statement, including liabilities under the Securities Act.

PLAN OF DISTRIBUTION

The term "selling security holder" includes the selling security holders listed herein and their pledgees, donees, transferees or other successors in interest. The selling security holders may, from time to time, sell any or all of their shares of our common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling security holders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the date of this prospectus;
- broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling security holders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling security holders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling security holders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling security holders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling security holders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling security holders to include the pledgee, transferee or other successors in interest as selling security holders under this prospectus.

The selling security holders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling security holders have informed the Company that it does not have any agreement or understanding, directly or indirectly, with any person to distribute our common stock.

We are required to pay all fees and expenses incident to the registration of the shares. We also agree to indemnify the selling security holders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

At the time a particular offer of the securities is made by or on behalf of a selling security holder, to the extent required, a prospectus will be distributed which will set forth the number of shares being offered and the

terms of the offering, including the name or names of any underwriters, dealers or agents, if any, the purchase price paid by any underwriter for the shares purchased from the selling security holders and any discounts, commissions or concessions allowed or reallowed or paid to dealers, and the proposed selling price to the public. For transactions effected on or through Nasdaq, those requirements may be satisfied by our delivery of copies of this prospectus to Nasdaq in compliance with Securities Act Rule 153.

Whenever we are notified by the selling security holders that any material arrangement has been entered into with a broker-dealer, agent or underwriter for the sale of shares through a block trade, special offering,

exchange distribution or secondary distribution or a purchase by a broker-dealer, agent or underwriter, we will file a supplemental prospectus, if required, pursuant to Rule 424(c) under the Securities Act. The supplemental prospectus will disclose:

- the name of each such selling security holder and of each participating broker-dealer, agent or underwriter,
- the number of shares involved,
- the price at which the shares were sold,
- the commissions paid or discounts or concessions allowed to broker-dealer(s), agent(s) or underwriter(s) or other items constituting compensation or indemnification arrangements with respect to particular offerings, where applicable,
- that the broker-dealer(s), agent(s) or underwriter(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, as supplemented, and
- other facts material to the transaction.

Under the securities laws of certain states, the shares may be sold by selling security holders only through registered or licensed brokers or dealers. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Any shares of a selling security holder covered by this prospectus which qualify for sale pursuant to Rule 144 promulgated under the Securities Act of 1933 may be sold under Rule 144 rather than pursuant to this prospectus.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of such distribution. In addition, each selling security holder will be subject to applicable provisions of the Exchange Act and the associated rules and regulations under the Exchange Act, including Regulation M, which provisions may limit the timing of purchases and sales of shares of our common stock by the selling shareholders. We will make copies of this prospectus available to the selling security holders and have informed them of the need for delivery of copies of this prospectus to purchasers at or prior to the time of any sale of the shares.

LEGAL MATTERS

The validity of the shares offered hereby were passed upon for us by Ehrenreich Eilenberg & Krause LLP.

EXPERTS

Eisner LLP, independent auditors, have audited our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2002, as set forth in their report, which is incorporated by reference in this prospectus. Our financial statements are incorporated by reference in reliance on the report of Eisner LLP, given on their authority as experts in accounting and auditing.

AXONYX INC.

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February 13, 2004