

AXONYX INC  
Form S-3  
February 12, 2003

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Registration Statement No.

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**U.S. SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM S-3**

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.)

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**825 THIRD AVENUE, 40th FLOOR  
NEW YORK, NEW YORK 10022  
(212) 688-4770**

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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**Marvin S. Hausman, M.D., President & Chief Executive Officer**

**825 Third Avenue, 40th Floor  
New York, New York 10022  
(212) 688-4770**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**APPROXIMATE DATE OF PROPOSED SALE TO THE PUBLIC: From time to time after the effective date of this Registration Statement.**

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration number of the earlier registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box:

**CALCULATION OF REGISTRATION FEE**

| Title of each Class of Securities to be Registered           | Amount to be Registered(1) | Proposed Maximum Offering Price Per Share(2)(3) | Proposed Maximum Aggregate Offering Price(2)(3) | Amount of Registration Fee |
|--|----------------------------|---|---|----------------------------|
| Common Stock, par value \$0.001 per share                    | 6,486,242                  | \$0.895   | \$5,805,187                                     | \$534.08                   |
| Common stock reserved for issuance upon exercise of warrants | 3,243,121                  | \$0.688   | \$2,231,267                                     | \$205.28                   |
| Common stock reserved for issuance upon exercise of warrants | 200,000                    | \$1.00  | \$200,000                                       | \$18.40                    |
| <b>Total</b>   | <b>9,929,363</b>           |   | <b>\$8,236,454</b>                              | <b>\$757.76</b>            |

- (1) Pursuant to Rule 416, there are also being registered additional shares of common stock that may be issuable under the anti-dilution provisions of the warrants.
- (2) The price of \$0.895, the average of the high and low prices of Axonyx's common stock on the Nasdaq National Market on February 7, 2003, is set forth solely for the purpose of computing the amount of the registration fee in accordance with Rule 457(c) under the Securities Act of 1933.
- (3) Pursuant to Rule 457(g), the registration fee for the common stock reserved for issuance upon exercise of warrants is calculated based on the exercise price of the respective warrants.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SECTION 8(a), MAY DETERMINE.

**Subject to completion, dated February 10, 2003.**

The information in this prospectus is not complete and may be changed. The selling security holders named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell or a solicitation of an offer to buy these securities in any state where the offer or sale is not permitted.

**Preliminary Prospectus**

**AXONYX INC.**

**9,929,363 shares of common stock**

This prospectus covers the offer and sale of up to 9,729,363 shares of common stock of Axonyx Inc. from time to time by certain selling security holders named in this prospectus.

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The shares being offered by the selling security holders include:

6,486,242 shares of our issued and outstanding common stock currently held by the selling security holders; and

3,443,121 shares of common stock issuable upon exercise of outstanding warrants to purchase common stock.

You should read this document and any prospectus supplement or amendment carefully before you invest.

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.

Our common stock is traded on the Nasdaq National Market under the symbol "AXYX". On February 7, 2003, the last reported sale price for our common stock was \$0.80 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 these securities, or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 10, 2003

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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>.

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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, 2001 (file no. 000-25571);
2. Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2002, June 30, 2002, and September 30, 2002;
3. Our Current Reports on Form 8-K dated March 6, 2002, December 20, 2002 and January 8, 2003;
4. Our Proxy Statement dated May 20, 2002; and
5. 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.  
825 Third Ave., 40<sup>th</sup> Floor  
New York, New York 10022  
Attention: Michael Espey, Vice President & General Counsel  
Telephone (212) 688-4770.

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### 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. We licensed these patent rights from New York University and, via a sublicense, from the National Institutes of Health/National Institute on Aging. We have an exclusive option to acquire patent rights to another potential pharmaceutical compound named Gilatide that is designed to enhance memory and cognition with potential applications to the treatment of AD. We also have co-inventorship rights to a therapeutic compound named Posiphen designed for the treatment of Alzheimer's Disease.

We out-source much of our preclinical and clinical research and development, utilizing contracting research organizations. 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 is undertaking research on certain of our licensed technologies. We received an up-front fee, and may receive milestone payments and royalties, under the License Agreement. We are sponsoring research at Thomas Jefferson University on a potential pharmaceutical compound named Gilatide and related analog compounds that are designed to enhance memory and cognition. We intend to develop other corporate partnerships with established and well capitalized pharmaceutical companies for the pre-clinical

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and/or clinical development of our compounds and for their potential production, commercialization and marketing. However, we cannot assure you we will be successful in establishing these relationships. 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. We are planning to initiate a Phase II clinical trial that will 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. We are also planning, given sufficient financial resources, to undertake a Phase III potentially pivotal clinical trial to further examine the safety and efficacy of Phenserine.

In addition to the Phenserine clinical program, we are continuing to sponsor pre-clinical research relating to (1) Gilatide, a potential pharmaceutical compound designed to enhance memory and cognition with potential applications to the treatment of AD, and (2) an assay method for screening drug candidates for Alzheimer's Disease. Pursuant to a sublicense agreement with ARS, ARS is undertaking 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. 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.

The AD targeted approaches include:

- (1) Phenserine, an inhibitor of acetylcholinesterase, 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) Gilatide, a potential pharmaceutical compound designed to enhance memory and cognition with potential applications to the treatment of AD;
- (4) Posiphen, a compound that decreases the formation of beta-amyloid precursor protein;
- (5) 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 PIP technologies. 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 may generate additional revenues from ARS if certain development milestones are reached concerning the licensed compounds or other products and related intellectual property, although such milestone payments may not occur in fiscal year 2003 or at all. 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 is conducting research and development work on compounds called Prion Inhibitory Peptides (PIPs) designed for the diagnosis and treatment of prion diseases such as Bovine Spongiform Encephalopathy (also known as Mad Cow Disease) and the human form of the disease, Creutzfeldt Jakob Disease, new variant.

On April 1, 2001, we entered into a Research Agreement with Thomas Jefferson University under which we agreed to fund a Gilatide Research Program for two years at a cost of \$125,000 per year. The research program concerns a potential pharmaceutical compound named Gilatide and related analog compounds that are designed to enhance memory and cognition. In addition, Thomas Jefferson University granted us an option to acquire from the University a worldwide exclusive license to a patent application pertaining to the Gilatide technology and to any invention arising out of the research program.

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On March 22, 2002, we filed a provisional patent application resulting from a collaboration between Gosse Bruinsma, M.D. of Axonyx and Dr. Nigel Greig of the NIH/NIA, on a co-inventorship basis, covering a method for treating patients with Alzheimer's Disease and other cognitive disorders with Posiphen, a potential pharmaceutical compound that is the positive isomer of Phenserine. Posiphen, unlike Phenserine, is not an acetylcholinesterase inhibitor. Posiphen's mechanism of action results in decreases in the formation of the beta-amyloid precursor protein through RNA translational inhibition. Axonyx and the NIH/NIA jointly own this patent application. Depending on the availability of financial resources, we may pursue pre-clinical testing of Posiphen.

Effective September 1, 2002, we entered into a Research Agreement and a Consulting Agreement with David Henry Small, Ph.D., and an Intellectual Property Assignment Agreement with David Henry Small, Ph.D., Marie-Isabel Aquilar, Ph.D., Supundi Subasinghe ("Assignment Agreement"). Each of these agreements relate to the development of an assay method for the rapid screening of potential drug candidates for the treatment of Alzheimer's Disease. The Research Agreement funds a research project concerning further development of the assay method under the guidance of Dr. Small for a three year period commencing October 1, 2002, for Australian \$90,000 per year. Under the Assignment Agreement Dr. Small and two other co-inventors have assigned a patent application concerning the

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assay method in return for revenue sharing upon commercialization of the assay method. Under the Consulting Agreement with Dr. Small, we engaged Dr. Small for a three year period for Australian \$20,000 per year and a grant of stock options for consulting services related to the development of the assay method.

Axonyx was incorporated in Nevada on July 29, 1997. Our principal executive offices are located at 825 Third Avenue, 40<sup>th</sup> Floor, New York, New York 10022, and our telephone number is (212) 688-4770.

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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 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

##### **If we need additional funds and 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. Therefore, we expect that we will need additional future financings to fund our operations. We anticipate that we will need to raise additional funds prior to commencing Phase III clinical trials, unless we receive significant revenue from milestone payments in 2003. We may not be able to obtain adequate financing to fund our operations, including any new clinical trials, and any additional financing we obtain may be on terms that are not favorable to us. In addition, any future 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), or to cease operations altogether.

**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 to date. As of September 30, 2002, we had an accumulated deficit of \$24,373,000 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 discovery 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 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

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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 \$1.75 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. We have not, as of the date this prospectus, received notice of default of any of our obligations. 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 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 most 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.

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**We do not currently have the capability to undertake manufacturing, marketing, or sales of any potential products and we have limited personnel to oversee 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 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 President and Chief Executive Officer, Dr. Marvin Hausman, and/or other executive officers would be detrimental to us. We currently have written employment agreements with only two of our executive officers. We do not have employment agreements with key scientific personnel who are doing research at the National Institute of Aging related to pharmaceutical compounds licensed via a sublicense to Axonyx, and have no assurance that such personnel will continue to be employed in such research.

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 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. In addition to the eight issued patents, we and our licensors have filed four patent applications in the United States. 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 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.

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. If our licensors elect to 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. 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.

**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, 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, Bisnorcymserine, or Posiphen 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.

We have engaged and intend to continue to engage third party contract research organizations and other third parties to help us develop our drug candidates. Although we have designed the clinical trials for our drug candidates, the contract research organizations 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 contract research organizations may not perform all of their obligations under arrangements with us. If the contract research organizations 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.

**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.

**Our controlling stockholders may make decisions that you do not consider to be in your best interest.**

As of January 31, 2003, our directors and executive officers beneficially owned approximately 20% of our outstanding common stock. As a result, our controlling stockholders are able to significantly influence all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions. This concentration of ownership could also delay or prevent a change in control of Axonyx that may be favored by other stockholders.

**We are significantly controlled by our management.**

Our executive officers comprise three of the six members of the Board of Directors. As a result, our management has the ability to exercise influence over our 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.

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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. 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.

Smaller companies may also prove to be significant competitors, particularly 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.

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 one 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 one of our drug product candidates has 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.

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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 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:

finances,

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

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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 may not be able to obtain 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 could be de-listed from Nasdaq if our appeal of a Nasdaq Staff Determination de-listing letter is rejected by the Nasdaq Listing Qualifications Panel or if the bid price of our common stock does not close above \$1.00 per share for at least ten consecutive trading days prior to March 17, 2003.**

On December 17, 2002 we received a Nasdaq Staff Determination letter indicating that we were not in compliance with the stockholders' equity requirements for continued listing on either The Nasdaq National Market or The Nasdaq SmallCap Market, and that our securities are, therefore, subject to de-listing. We have requested and attended a hearing before a Nasdaq Listing Qualifications Panel to review the Staff Determination. Our common stock could be de-listed from Nasdaq if, after a hearing before the Nasdaq Listing Qualifications Panel, the Panel rejects our appeal.

In addition, the Nasdaq Staff Determination letter notified us that the closing bid price of our common stock has closed below the minimum \$1.00 per share requirement for continued listing on either the Nasdaq National Market or The Nasdaq SmallCap Market for the 30 consecutive trading days prior to the date of the Staff letter. In accordance with Nasdaq rules we have been provided 90 calendar days, or until March 17, 2003, to regain compliance. If, at any time before March 17, 2003, the bid price of our common stock closes at \$1.00 per shares or more for a minimum of 10 consecutive trading days, we will be notified that we comply with the bid price provision of the above Rule. If we cannot demonstrate compliance with the Rule by March 17, 2003, we will be notified that our common stock will be de-listed from the Nasdaq National Market. At that time we may appeal the de-listing determination to a Listing Qualifications Panel.

If our common stock is no longer listed on the Nasdaq National Market or Nasdaq SmallCap Market, our common stock could trade in the over-the-counter market in the "pink sheets" maintained by Pink Sheets LLC or on the National Market Association of Securities Dealers' OTC Bulletin Board, which was established for securities that do not meet the Nasdaq listing requirements. Such alternative trading markets are generally considered less efficient than the Nasdaq National Market or Nasdaq SmallCap Market. Consequently, selling our common stock would be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed and securities' analysts and news media coverage of Axonyx may be reduced. These factors could result in lower prices and a larger spread in the bid and ask prices for shares of our common stock.

**We do not pay cash dividends.**

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

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**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 10.5 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. 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 National Market under the symbol "AXYX" with very limited trading volume. We cannot assure you that a substantial trading market will ever develop (or be sustained, if developed) 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."

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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.

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### **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, 2003, we had outstanding options to purchase an aggregate of 3,510,600 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 1,239,400 shares of our common stock under the 2000 and 1998 Stock Option Plans.

In addition, we have granted options to purchase an aggregate of 129,000 shares of common stock outside of our Stock Option Plans to consultants and others.

There are currently outstanding warrants to purchase an aggregate of 5,421,121 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. 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.

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**SELLING SECURITY HOLDERS**

On December 31, 2002, we closed a private placement of 6,486,242 shares of common stock and warrants to purchase an additional 3,243,121 shares of common stock. This prospectus covers the 6,486,242 common shares and the 3,243,121 warrant shares, as well as 200,000 shares of common stock issuable upon the exercise of warrants issued to AFO Advisors, LLC as part of a fee 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 KCM Biomedical LP (4.40%), Joseph Edelman/Perceptive Life Sciences Master Fund (2.11%), KCM Biomedical Offshore Master Fund (1.39%), and AFO Advisor, LLC/AFO Capital Advisors, LLC/Amy Factor (1.20%).

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.

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

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books and records, as well as from our transfer agent. The following table assumes the sale of all shares included in this prospectus.

| Selling Security Holder                              | Shares Owned<br>Prior to this<br>Offering | Shares Available<br>Pursuant to this<br>Prospectus | Shares Owned<br>After Offering |
|--|---|--|--------------------------------|
| AFO Advisors, LLC(1)                                 | 389,500                                   | 200,000  | 189,500                        |
| AFO Capital Advisors, LLC                            | 196,087                                   | 99,933   | 96,154                         |
| Clarion Capital                                      | 499,667                                   | 499,667  | 0                              |
| Clearwater Fund I, LP                                | 303,000                                   | 303,000  | 0                              |
| Clearwater Offshore Fund, LTD                        | 202,500                                   | 202,500  | 0                              |
| Edelman, Joseph (2)                                  | 1,702,601                                 | 1,199,334  | 503,267                        |
| Gelman, Marc   | 249,833                                   | 249,834  | 0                              |
| Gotham Asset Management Master Fund                  | 199,867                                   | 199,867  | 0                              |
| Heller, Daniel                                       | 45,000                                    | 45,000   | 0                              |
| KCM Biomedical LP                                    | 1,539,000                                 | 300,000  | 1,059,000                      |
| KCM Biomedical II LP                                 | 84,000                                    | 42,000   | 42,000                         |
| KCM Biomedical Offshore Master Fund                  | 442,500                                   | 108,000  | 334,500                        |
| Knightsbridge Integrated Holdings V                  | 282,000                                   | 282,000  | 0                              |
| Knightsbridge Integrated Holdings IV Post Venture LP | 214,500                                   | 214,500  | 0                              |
| Knightsbridge Integrated Holdings II Limited         | 232,500                                   | 232,500  | 0                              |

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| Selling Security Holder                  | Shares Owned<br>Prior to this<br>Offering | Shares Available<br>Pursuant to this<br>Prospectus | Shares Owned<br>After Offering |
|--|---|--|--------------------------------|
| Knightsbridge Netherlands I, LP          | 136,500                                   | 136,500  | 0                              |
| Knightsbridge Netherlands II, LP         | 123,000                                   | 123,000  | 0                              |
| Knightsbridge Netherlands III, LP        | 34,500                                    | 34,500   | 0                              |
| Knightsbridge Post Venture III, LP       | 220,500                                   | 220,500  | 0                              |
| Knightsbridge Post Venture IV, LP        | 378,000                                   | 378,000  | 0                              |
| Louis Cornacchia IRA                     | 222,087                                   | 99,933   | 122,154                        |
| Oliveira, Steve                          | 653,000                                   | 600,000  | 53,000                         |
| Orion Biomedical Fund LP                 | 820,953                                   | 820,953  | 0                              |
| Orion Biomedical Offshore Fund LP        | 178,382                                   | 178,382  | 0                              |
| Pomper, Alexander                        | 450,000                                   | 450,000  | 0                              |
| Perceptive Life Sciences Master Fund (2) | 1,449,934                                 | 999,334  | 450,600                        |
| Quoque Capital LLC                       | 741,650                                   | 600,000  | 141,650                        |
| Sankin, Andrew                           | 59,960                                    | 59,960   | 0                              |
| Seringer, Joseph                         | 111,933                                   | 99,933   | 12,000                         |
| Shelton, Elliot                          | 249,833                                   | 249,834  | 0                              |
| Tabuteau, Herriot                        | 1,508,000                                 | 1,500,000  | 8,000                          |
| William S. Fagan IRA                     | 199,867                                   | 199,867  | 0                              |

- (1) AFO Advisors, LLC is a consultant to Axonyx Inc. 200,000 common stock purchase warrants were acquired by AFO Advisors in relation to a fee payable upon the closing of private placement on December 31, 2002. The warrants issued to AFO Advisors, LLC are exercisable at \$1.00 per share. Amy Factor is the principal of AFO Advisors, LLC and of AFO Capital Advisors, LLC. AFO Capital Advisors purchased 66,622 shares and warrants to purchase 33,311 shares in the private placement that closed on December 31, 2002. AFO Capital Advisors also holds 96,154 shares acquired in previous transactions. Amy Factor holds 500 shares acquired previously and options to purchase 189,000 shares that are vested or will vest within 60 days.
- (2) According to a Schedule 13G filed by Joseph Edelman dated January 31, 2003, Joseph Edelman is the beneficial owner of 1,702,601 shares of common stock of Axonyx Inc. comprised of (i) 133,245 shares and warrants to purchase 66,622 shares held by Mr. Edelman, (ii) 1,041,823 shares and warrants to purchase 408,111 shares held by Perceptive Life Sciences Master Fund Ltd., the

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investment manager of which is Perceptive Advisors LLC, a Delaware limited liability company, of which Mr. Edelman is the managing member and (iii) 52,800 shares held in a trading account of which Mr. Edelman has sole voting and dispositive power.

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 shares offered hereby by the selling security holders may be sold from time to time by the selling security holders. 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 will act independently of us in making decisions with respect to the timing, manner and size of each sale. The distribution of the securities by the selling security holders may be effected in one or more transactions that may take place on the Nasdaq

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National Market or on any other organized market or quotation system where the shares may be traded, on the over-the-counter market, in transactions otherwise than on the Nasdaq National Market or on any other organized market or quotation system or the over-the-counter market, in negotiated transactions or otherwise, including ordinary broker's transactions or, through sales to one or more broker-dealers for resale of the shares as principals, at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at negotiated prices. The securities may also be transferred pursuant to a gift or pledge. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling security holders in connection with the sales of securities. The selling security holders and any brokers, dealers or agents and any other participating brokers or dealers may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act in connection with the sale of the shares. Accordingly, any fee, commission, discount or concession received by them may be deemed to be underwriting discounts or commissions under the Securities Act.

The shares offered by the selling security holders may be sold by one or more methods, including without limitation:

block transactions;

transactions effected with or through a broker-dealer acting either as agent or principal;

ordinary brokerage transactions and transactions in which the broker may solicit purchases;

face-to-face transactions between sellers and purchasers without a broker-dealer; and

any combination of any such methods of sale.

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In connection with the sale of shares, the selling security holders may enter into hedging transactions. For example, the selling security holders may, among other things:

enter into transactions involving short sales of the common stock by broker-dealers;

sell common stock short themselves and deliver the shares registered hereby to settle such short sales or to close out stock loans incurred in connection with their short positions;

enter into put or call options or other types of transactions that require the selling security holder to deliver common stock to a broker-dealer or other person, who may then resell or transfer the common stock under this prospectus;

loan or pledge the common stock to a broker-dealer or other person, who may sell the loaned shares or, in the event of default, sell the pledged shares; or

any combination of any such transactions.

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 reallocated 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

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broker-dealer, agent or underwriter, we will file a supplemental prospectus, if required, pursuant to Rule 424(c) under the 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

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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, under Nevada law, were passed upon for us by Gordon & Silver, Ltd.

### EXPERTS

Eisner LLP, formerly known as Richard A. Eisner & Company, LLP, independent auditors, have audited our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2001, 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.

### PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

**Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth all expenses payable by the Registrant in connection with the sale of the common stock being registered. All the amounts shown are estimates, except for the registration fee.

|                                    |           |
|------------------------------------|-----------|
| SEC Registration Fee               | \$ 757.76 |
| Legal Fees and Expenses*           | 57,000    |
| Accounting Fees and Expenses*      | 3,000     |
| Printing Fees*                     | 1,000     |
| Transfer Agent and Registrar Fees* | 1,000     |
| Nasdaq Filing Fees*                | 22,500    |
| Miscellaneous Expenses*            | 742.24    |
|                                    | <hr/>     |
| TOTAL                              | \$ 86,000 |
|                                    | <hr/>     |

\* Estimated.

**Item 15. Indemnification of Officers and Directors.**

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:

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.

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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.

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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 16. Exhibits and Financial Statement Schedules.

#### (a) Exhibits.

| Exhibit No. | Description   |
|-------------|---|
| 3.1*        | Restated Articles of Incorporation dated June 23, 2000                    |
| 3.2**       | By-Laws   |
| 4.1***      | Form of Common Stock Purchase Warrant                                     |
| 4.2         | Form of Warrant (AFO Advisors, LLC)                                       |
| 5.1         | Opinion of Gordon & Silver, Ltd.  |
| 10.1+       | Common Stock and Warrant Purchase Agreement dated as of December 31, 2002 |
| 23.1        | Consent of Eisner LLP, Independent Auditors                               |
| 23.2        | Consent of Gordon & Silver, Ltd. (included in Exhibit 5.1)                |
| 24.1        | Power of Attorney (included on page II-5 of this Registration Statement)  |

\*  
Incorporated by reference to the corresponding exhibit in the Form 10-QSB previously filed by Axonyx on August 14, 2000 (File no. 00025571).

\*\*  
Incorporated by reference to the corresponding exhibit in the Registration Statement on Form 10-SB previously filed by Axonyx on March 17, 1999 (File no. 00025571).

\*\*\*  
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### Item 17. Undertakings.

## Edgar Filing: AXONYX INC - Form S-3

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 of 1933;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the 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 the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

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- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*provided, however*, that paragraphs (1)(i) and (1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement;

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, 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.

The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the 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 of 1933 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 SEC such indemnification is against public policy as expressed in the Securities Act of 1933 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 question has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

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**SIGNATURES**

## Edgar Filing: AXONYX INC - Form S-3

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-3 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 10th day of February, 2003.

AXONYX INC

By: \_\_\_\_\_ /s/ MARVIN S. HAUSMAN, M.D.

Marvin S. Hausman, M.D.

*President and Chief Executive Officer*

We, the undersigned, hereby severally constitute and appoint Marvin S. Hausman, M.D. and Michael R. Espey 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 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 this capacities and on the dates indicated:

| <u>Signature</u>                         | <u>Title</u>  |                   |
|--|---|-------------------|
| _____<br><br>/s/ ALBERT D. ANGEL         |   |                   |
| _____<br>Albert D. Angel                 | Chairman of the Board   | February 10, 2003 |
| _____<br><br>/s/ MARVIN S. HAUSMAN, M.D. |   |                   |
| _____<br>Marvin S. Hausman, M.D.         | President and Chief Executive Officer and<br>Director (Principal Executive Officer)             | February 10, 2003 |
| _____<br><br>/s/ GOSSE B. BRUINSMA, M.D. |   |                   |
| _____<br>Gosse B. Bruinsma, M.D.         | Chief Operating Officer, Treasurer and Director<br>(Principal Financial and Accounting Officer) | February 10, 2003 |
| _____<br><br>/s/ MICHAEL R. ESPEY        |   |                   |
| _____<br>Michael R. Espey                | Vice President, Secretary, General Counsel and<br>Director                                      | February 10, 2003 |
| _____<br><br>/s/ ABRAHAM E. COHEN        |   |                   |
| _____<br>Abraham E. Cohen                | Director  | February 10, 2003 |
| _____<br><br>/s/ STEVEN H. FERRIS        |   |                   |
| _____<br>Steven H. Ferris                | Director  | February 10, 2003 |

### EXHIBIT INDEX

**Exhibit No.      Description**



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|        |   |
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SIGNATURES

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