

AXONYX INC
Form 10-K/A
March 30, 2005

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 10-K/A

(Amendment No.1)

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

For the fiscal year ended December 31, 2004

OR

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

For the transition period from _____ To _____

Commission file number: 000-25571

AXONYX INC.

500 Seventh Avenue, 10th Floor

New York, New York 10018

Telephone (212) 645-7704

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

State or Other jurisdiction of Incorporation or Organization: Nevada

Securities registered under Section 12(g) of the Exchange Act: Common Stock \$0.001 par value

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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Indicate by check mark whether registrant is an accelerated filer (as defined in Rule 12b-2 of the Act).

Yes No

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

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

Documents incorporated by reference: None.

EXPLANATORY NOTE

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

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

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

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

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

Management's Annual Report on Internal Control Over Financial Reporting

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

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

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

Attestation Report of the Registered Public Accounting Firm

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

Changes in Internal Control Over Financial Reporting

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting, that Axonyx, Inc. (the Company) maintained effective internal control over financial reporting as of December 31, 2004, based on, criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Axonyx, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

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

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

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

EISNER LLP

New York, New York

March 28, 2005

Item 15. Exhibits and Financial Statement Schedules
Consolidated Financial Statements (previously filed with Form 10-K):

Report of Independent Registered Public Accounting Firm
Balance sheets as of December 31, 2004 and 2003
Statements of operations for each of the years in the three-year period ended December 31, 2004
Statements of changes in stockholders' equity for each of the years in the three-year period ended

December 31, 2004
Statements of cash flows for each of the years in the three-year period ended December 31, 2004
Notes to consolidated financial statements

Exhibits:

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

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- 4.8 Form of Warrant (AFO Advisors, LLC) (Incorporated by reference to Exhibit 4.2 in the registration statement on Form S-3 previously filed by Axonyx on February 12, 2003 (File No. 333-103130))
- 4.9 Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 10.2 in the current report on Form 8-K previously filed by Axonyx on September 16, 2004 (File No. 00025571))
- 4.10 Form of Warrant (Incorporated by reference to Exhibit 4.3 in the current report on Form 8-K previously filed by Axonyx on January 12, 2004 (File No. 00025571))
- 4.11 Registration Rights Agreement dated as of January 8, 2004 between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.2 in the current report on Form 8-K previously filed by Axonyx Inc. on January 12, 2004)
- 4.12 Registration Rights Agreement dated as of May 3, 2004, between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.2 in the current report on Form 8-K previously filed by Axonyx Inc. on May 5, 2004)
- 10.1 1998 Stock Option Plan (Incorporated by reference to the corresponding exhibit to the March 17, 1999 10-SB)
- 10.2(a) 2000 Stock Option Plan (Incorporated by reference to exhibit 99.2 to the Registration on Form S-8 previously filed by Axonyx on October 17, 2000 (file number 333-48088))
- 10.2(b) First Amendment to 2000 Stock Option Plan (Incorporated by reference to the corresponding exhibit to Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.2(c) Second Amended and Restated 2000 Stock Option Plan (Incorporated by reference to Appendix E to Schedule 14A previously filed by the Company on May 14, 2004)
- 10.3(a) Patent License Agreement - Exclusive between the Public Health Service and CURE, LLC dated January 31, 1997 (Incorporated by reference to exhibit 10.2 to the Registration Statement on Form 10-SB Amendment No. 1 previously filed by Axonyx on August 10, 1999 (File no. 000-25571) (the August 10, 1999 10-SB/A))
- 10.3(b) License Agreement between the Axonyx Inc. and CURE, LLC dated February 27, 1997 (Incorporated by reference to exhibit 10.2 to the March 17, 1999 10-SB)
- 10.3(c) Letter Amendment of License Agreement between Axonyx Inc. and CURE, LLC dated May 27, 2002 (Incorporated by reference to exhibit 10.1 to Form 10-Q previously filed on August 14, 2002 (File No. 000-25571))
- 10.4 Research and License Agreement between the Axonyx Inc. and New York University dated April 1, 1997 (Incorporated by reference to exhibit 10.3 to the March 17, 1999 10-SB)
- 10.5 Second Amendment to Research and License Agreement between Axonyx Inc. and New York University dated March 19, 1999 (Incorporated by reference to exhibit A to the Quarterly Report on Form 10-Q previously filed by Axonyx on June 30, 1999)
- 10.6 Fourth Amendment to Research and License Agreement between Axonyx Inc. and New York University dated October 11, 2002 (Incorporated by reference to exhibit 10.1 to Form 10-Q previously filed on November 14, 2002 (File No. 000-25571))
- 10.7 Financial Consulting Agreement between Axonyx Inc. and Intertrend Management, Ltd. dated November 6, 1998 (Incorporated by reference to exhibit 10.7 in the August 10, 1999 10-SB/A)
- 10.8 Development Agreement and Right to License between Axonyx Inc. and Applied Research Systems ARS Holding N.V. dated May 17, 1999 (Incorporated by reference to exhibit 99(c) to the Current Report on Form 8-K previously filed by Axonyx on June 1, 1999)

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10.9 License Agreement between Axonyx Inc. and Applied Research Systems ARS N.V. dated September 15, 2000 (Incorporated by reference to exhibit 10.9 to the March 22, 2001 10-KSB)

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- 10.10 Sponsored Research Agreement between the University of Melbourne and Axonyx Inc. dated October 1, 1999 (Incorporated by reference to exhibit 10.10 to the March 22, 2001 10-KSB)
- 10.11 Common Stock Underwriting Agreement between Ramius Securities, LLC and Axonyx Inc. dated October 25, 2000 (Incorporated by reference to exhibit 10.11 to the March 22, 2001 10-KSB)
- 10.12 Stand-By Purchase Agreement between Ramius Capital Group, LLC and Axonyx Inc. dated October 25, 2000 (Incorporated by reference to exhibit 10.12 to the March 22, 2001 10-KSB)
- 10.13 Lease Agreement between Axonyx Inc. and Business Service Center of Seattle dated January 28, 1999 (Incorporated by reference to exhibit 10.5 to the March 17, 1999 10-SB)
- 10.14 Occupancy Agreement between Axonyx Inc., J.A. Bernstein & Co. and The Garnet Group, Inc. dated December 14, 1999 (Incorporated by reference to exhibit 10.10 to the March 13, 2000 10-KSB)
- 10.15 Letter Agreement between Axonyx Inc. and J.A. Bernstein & Co. dated December 9, 1999 (Incorporated by reference to exhibit 10.11 to the March 13, 2000 10-KSB)
- 10.16 Data Management and Reporting Services Agreement between Axonyx Inc. and Clinfo Systems, LLC dated October 2, 2000 (Incorporated by reference to the corresponding exhibit to the Annual Report on Form 10-KSB Amendment No. 1 previously filed by Axonyx on May 15, 2001 (the May 15, 2001 10-KSB/A)
- 10.17 Data Management and Reporting Services Agreement between Axonyx Inc. and Clinfo Systems, LLC dated January 2, 2001 (Incorporated by reference to the corresponding exhibit to the May 15, 2001 10-KSB/A)
- 10.18 Research Agreement between Thomas Jefferson University and Axonyx Inc. dated as of April 1, 2001 (Incorporated by reference to exhibit 10.1 to the Quarterly Report on Form 10-Q previously filed by Axonyx on May 15, 2001)
- 10.19 Sponsored Research Agreement and Option between Mayo Foundation for Medical Education and Research, Mayo Clinic Jacksonville and Axonyx Inc. dated May 1, 2001 (Incorporated by reference to the corresponding exhibit to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.20 Research Agreement between Indiana University and Axonyx Inc. dated August 15, 2001 (Incorporated by reference to the corresponding exhibit to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.21 Common Stock and Warrant Purchase Agreement dated December 4, 2001 (Incorporated by reference to exhibit 10.1 to the December 13, 2001 8-K)
- 10.22** Employment Agreement by and between Axonyx Europe B.V. and Dr. Gosse Bruinsma dated October 10, 2000 (Incorporated by reference to exhibit 10.22 to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.23** Letter Agreement between Axonyx Inc. and Dr. Robert Burford dated November 10, 1999 (Incorporated by reference to exhibit 10.23 to the Form 10-K previously filed on March 28, 2002 (File No. 000-25571))
- 10.24 Research Agreement between David Henry Small, Ph.D. and Axonyx Inc. dated September 1, 2002 (Incorporated by reference to exhibit 10.2 to Form 10-Q previously filed on November 14, 2002 (File No. 000-25571))
- 10.25 Intellectual Property Assignment Agreement between David Henry Small, Ph.D., Marie-Isabel Aguilar, Ph.D., Supundi Subasinghe and Axonyx Inc. dated September 1, 2002 (Incorporated by reference to exhibit 10.3 to Form 10-Q previously filed on November 14, 2002 (File No. 000-25571))
- 10.26 Common Stock and Warrant Purchase Agreement dated as of December 31, 2002 (Incorporated by reference to Exhibit 10.1 in the Form 8-K previously filed by Axonyx on January 8, 2003 (File No. 00025571))

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- 10.27 Clinical Trial Services Master Agreement between JSW Research and Axonyx Inc. dated March 21, 2003 (Incorporated by reference to Exhibit 10.27 in the Form 10-K previously filed by Axonyx on March 31, 2003 (File No. 00025571))
- 10.28 Contract between Axonyx Europe and NOTOX Safety and Environmental Research B.V. dated April 11, 2002 (Incorporated by reference to Exhibit 10.28 in the Form 10-K previously filed by Axonyx on March 31, 2003 (File No. 00025571))
- 10.29 Common Stock and Warrant Purchase Agreement dated as of September 11, 2003 (Incorporated by reference to Exhibit 10.1 in the current report on Form 8-K previously filed by Axonyx on September 16, 2004 (File No. 00025571))
- 10.30 Securities Purchase Agreement dated as of January 8, 2004 (Incorporated by reference to Exhibit 4.1 in the current report on Form 8-K previously filed by Axonyx on January 12, 2004 (File No. 00025571))
- 10.31 Share Exchange Agreement dated as of January 15, 2004 between Axonyx Inc. and Oxis International, Inc., (incorporated by reference to Exhibit 10.1 in the current report on Form 8-K previously filed by Axonyx Inc. on January 20, 2004)
- 10.32** Change of Control Agreement dated as of March 30, 2004 between Axonyx and Marvin S. Hausman (incorporated by reference to Exhibit 10.32 of Axonyx Inc. s Annual Report on Form 10-K for the fiscal year ended December 31, 2003)
- 10.33** Change of Control Agreement dated as of March 30, 2004 between Axonyx and Gosse Bruinsma (incorporated by reference to Exhibit 10.33 of Axonyx Inc. Inc. s Annual Report on Form 10-K for the fiscal year ended December 31, 2003)
- 10.34** Change of Control Agreement dated as of March 30, 2004 between Axonyx and S. Colin Neill (incorporated by reference to Exhibit 10.34 of Axonyx Inc. s Annual Report on Form 10-K for the fiscal year ended December 31, 2003)
- 10.35 Securities Purchase Agreement dated as of May 3, 2004 between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.1 in the current report on Form 8-K previously filed by Axonyx Inc. on May 5, 2004)
- 14 Code of Business Conduct and Ethics***
- 21 List of Subsidiaries (Incorporated by reference to the corresponding exhibit to the March 22, 2001 10-KSB)
- 23.1 Consent of Eisner LLP*
- 31.1 Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer*
- 31.2 Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer*
- 32 Section 1350 Certification of Chief Executive Officer and Chief Financial Officer*

* Filed herewith

** Indicates management compensation agreement

*** Previously filed

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

SIGNATURE

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

AXONYX INC.

By: /s/ S. Colin Neill
S. Colin Neill
Chief Financial Officer