

AXONYX INC
Form 10-Q
May 14, 2004

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2004

Commission file number: 000-25571

AXONYX INC.
(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction of Incorporation)

86-0883978
(IRS Employer Identification No.)

500 Seventh Avenue, 10th Floor, New York, New York
(Address of Principal Executive Offices)

10018
(Zip Code)

Registrant's telephone number, including area code (212) 645-7704

Indicate by a check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by a check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 13, 2004, there were 51,233,773 shares of the registrant's common stock outstanding.

AXONYX INC.

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Condensed Consolidated Balance Sheets as of March 31, 2004 (unaudited)
and December 31, 2003 1

Condensed Consolidated Statements of Operations (unaudited) for the three
months ended March 31, 2004 and 2003 2

Condensed Consolidated Statements of Changes in Stockholders' Equity
(unaudited) for the three months ended March 31, 2004 3

Edgar Filing: AXONYX INC - Form 10-Q

	<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2004 and 2003</u>	4
	<u>Notes to Condensed Consolidated Financial Statements</u>	5
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	9
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	16
Item 4.	<u>Controls and Procedures</u>	17
PART II.	<u>OTHER INFORMATION</u>	18
Item 6.	<u>Exhibits and Reports on Form 8-K</u>	18
	<u>Signatures</u>	20

PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

AXONYX INC.

Condensed Consolidated Balance Sheets

	March 31, 2004	December 31, 2003
	(unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 80,640,000	\$ 28,780,000
Accounts receivable	291,000	
Inventories	270,000	
Other current assets	369,000	
	<hr/>	<hr/>
Total current assets	81,570,000	28,780,000
Equipment, net	58,000	24,000
Technology for developed products, net	7,432,000	
Patents and patents pending, net	816,000	
Security deposit	18,000	11,000
	<hr/>	<hr/>
	\$ 89,894,000	\$ 28,815,000
	<hr/>	<hr/>

LIABILITIES

Current liabilities:

Edgar Filing: AXONYX INC - Form 10-Q

	March 31, 2004	December 31, 2003
Accounts payable	\$ 2,941,000	\$ 1,284,000
Accrued expenses	1,266,000	880,000
Note payable	160,000	
Convertible bridge loans	119,000	
Total liabilities	4,486,000	2,164,000
Minority interest in subsidiary	404,000	
STOCKHOLDERS' EQUITY		
Preferred stock - \$.001 par value, 15,000,000 shares authorized; none issued		
Common Stock - \$.001 par value, 75,000,000 shares authorized; 47,978,540 and 33,919,948 shares issued and outstanding in 2004 and 2003 respectively.	48,000	34,000
Additional paid-in capital	124,917,000	60,345,000
Unearned compensation - stock options	(242,000)	
Accumulated deficit	(39,719,000)	(33,728,000)
Total stockholders' equity	85,004,000	26,651,000
Total liabilities and stockholders' equity	\$ 89,894,000	\$ 28,815,000

See notes to condensed consolidated financial statements.

1

AXONYX INC.

Condensed Consolidated Statements of Operations
(unaudited)

	Three months ended March 31,	
	2004	2003
Revenue	\$ 478,000	
Cost of revenue	266,000	
Gross profit	212,000	
Costs and expenses:		
Research and development	4,053,000	\$ 1,027,000
Sales, general and administrative	2,371,000	573,000
	6,424,000	1,600,000

Edgar Filing: AXONYX INC - Form 10-Q

	Three months ended March 31,	
Loss from operations	(6,212,000)	(1,600,000)
Other income (expense)		
Interest income	185,000	22,000
Foreign exchange	(71,000)	3,000
Financing fees	(136,000)	
Interest expense	(12,000)	
Net loss before minority interest in subsidiary	(6,246,000)	(1,575,000)
Minority interest in loss of subsidiary	255,000	
Net loss	\$ (5,991,000)	\$ (1,575,000)
Net loss per common share	\$ (0.13)	\$ (0.07)
Weighted average shares-basic and diluted	45,160,000	23,746,000

See notes to condensed consolidated financial statements.

2

AXONYX INC.

Condensed Consolidated Statements of Changes in Stockholders' Equity
(unaudited)

	Common Stock			Unearned Compensation Stock Options	Accumulated Deficit	Total Stockholders Equity
	Number of Shares	Amount	Additional Paid-in Capital			
Balance - December 31, 2003	33,919,948	\$ 34,000	\$ 60,345,000	\$	\$ (33,728,000)	\$ 26,651,000
Issuance of common stock and warrants - net of expenses	9,650,183	10,000	46,384,000			46,394,000
Issuance of common stock for the acquisition of 53% of Oxis International Inc.	1,618,061	1,000	8,193,000			8,194,000
Issuance of common stock options and warrants for consulting services			710,000			710,000
Issuance of common stock for consulting services	25,000		197,000			197,000

AXONYX INC.

Edgar Filing: AXONYX INC - Form 10-Q

	<u>Common Stock</u>			<u>Unearned</u>		
Issuance of common stock options			387,000	(387,000)		
Exercise of common stock warrants and options	2,765,348	3,000	8,701,000			8,704,000
Amortization				145,000		145,000
Net loss					(5,991,000)	(5,991,000)
Balance - March 31, 2004	<u>47,978,540</u>	<u>\$ 48,000</u>	<u>\$ 124,917,000</u>	<u>\$ (242,000)</u>	<u>\$ (39,719,000)</u>	<u>\$ 85,004,000</u>

See notes to condensed consolidated financial statements.

3

AXONYX INC.

Condensed Consolidated Statements of Cash Flows
(unaudited)

	Three months ended March 31,	
	2004	2003
Cash flows from operating activities:		
Net Loss	\$ (5,991,000)	\$ (1,575,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	165,000	4,000
Minority interest in net loss of subsidiary	(255,000)	
Compensation related to common stock issued for services	210,000	56,000
Compensation related to options and warrants issued for services	855,000	49,000
Changes in:		
Accounts receivable	(24,000)	
Inventory	25,000	
Other current assets	(153,000)	(135,000)
Technology and patents	(49,000)	
Other assets	25,000	46,000
Accounts payable and accrued expenses	1,052,000	(758,000)
Accrued stock based compensation	111,000	2,000
Net cash used in operating activities	(4,029,000)	(2,311,000)
Cash flows from investing activities:		
Costs related to Oxis acquisition	(52,000)	
Purchase of equipment	(1,000)	
Net cash used in investing activities	(53,000)	
Cash flows from financing activities		
Net proceeds from issuance of common stock and warrants	46,394,000	

Edgar Filing: AXONYX INC - Form 10-Q

	Three months ended March 31,	
Net proceeds from exercise of common stock options and warrants	8,715,000	
Net bridge loan proceeds	119,000	
Collection of stock subscriptions receivable and cash held in escrow		4,868,000
	<hr/>	
Net cash provided from financing activities	55,228,000	4,868,000
Net increase in cash and cash equivalents	51,146,000	2,557,000
Cash and cash equivalents at beginning of period	29,494,000	3,021,000
	<hr/>	
Cash and cash equivalents at end of period	\$ 80,640,000	\$ 5,578,000
	<hr/>	
Supplemental disclosures of non-cash financing activity		
Common stock issued in connection with acquisition	\$ 8,194,000	
Unearned compensation recorded for common stock options issued	\$ 387,000	
Minority interest in subsidiary equity transactions	\$ 24,000	

See notes to condensed consolidated financial statements.

4

Notes to Condensed Consolidated Financial Statements

(1) Financial Statement Presentation

The unaudited condensed consolidated financial statements of Axonyx Inc. (the Company) herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) and, in the opinion of management, reflect all adjustments (consisting only of normal recurring accruals) necessary to present fairly the financial position at March 31, 2004 and the results of operations for the interim periods presented. Certain information and footnote disclosure normally included in the financial statements, prepared in accordance with accounting principles generally accepted in the United States of America, have been condensed or omitted pursuant to such rules and regulations. However, management believes that the disclosures are adequate to make the information presented not misleading. These financial statements and notes thereto should be read in conjunction with the financial statements and the notes thereto for the year ended December 31, 2003 included in the Company's Form 10-K filing. The results for the interim periods are not necessarily indicative of the results for the full fiscal year.

The condensed consolidated financial statements of Axonyx include the accounts of OXIS International Inc. (OXIS) from the acquisition date of January 15, 2004. The minority interest in the condensed consolidated financial statements represents the minority stockholders proportionate share of equity in OXIS. All significant inter-company accounts and transactions have been eliminated in consolidation.

(2) Acquisition of OXIS International, Inc.

On January 15, 2004 the Company entered into agreements to acquire approximately 53% of the outstanding voting stock of OXIS. OXIS is a biopharmaceutical company engaged in the development of research diagnostics, nutraceuticals and therapeutics in the field of oxidative stress. Under the terms of separate agreements entered into with several holders of OXIS common stock, the Company acquired an aggregate of approximately 14 million shares of OXIS stock, in consideration for the issuance of an aggregate of approximately 1.6 million shares of our unregistered common stock, which the Company registered in May 2004. The Company's Chairman and Chief Executive Officer owns 1,161,532 shares of OXIS common stock, representing approximately 4% of the OXIS's voting stock. Those shares of OXIS's common stock were not being acquired.

(2) Acquisition of OXIS International, Inc.

Edgar Filing: AXONYX INC - Form 10-Q

The aggregate purchase price was \$8,246,000, which includes the fair value of the Company's common shares that were issued as consideration and transaction costs.

The allocation of the cost of the acquisition is as follows:

Current assets	\$ 1,492,000
Equipment	41,000
Technology and developed products	7,622,000
Patents and other assets	765,000
Current liabilities	(1,039,000)
Minority interest	(635,000)
Deferred tax liability (1)	(3,011,000)
Deferred tax liability (2)	3,011,000
	<hr/>
	\$ 8,246,000
	<hr/>

5

- (1) Represents the tax effect of the excess of the financial statement basis over the tax basis for acquired technology for developed products.
- (2) Represents the tax benefit of OXIS net operating loss carryforward and deductible temporary differences recognized as an offset against the deferred tax liability attributable to the acquired technology for developed products.

The following proforma information gives effect to the acquisition as if it had occurred on the first day of each of the quarters ended March 31, 2004 and 2003.

	<u>March 31, 2004</u>	<u>March 31, 2003</u>
Total revenues	\$567,000	\$549,000
Net loss including minority interest in subsidiary	(6,362,000)	(1,907,000)
Net loss	(6,067,000)	(1,839,000)
Basic and diluted net loss per common share	(0.13)	(0.07)

(3) Stock-based Compensation

The Company follows the intrinsic value based method in accounting for stock-based employee compensation under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees", and related interpretations. The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standard (SFAS) No. 123, "Accounting for Stock-Based Compensation", and SFAS No. 148, "Accounting for Stock-Based Compensation: Transition and Disclosure". The Company follows the fair value based method for awards to non-employees.

The following table illustrates the effect on net loss and loss per share if the fair value based method had been applied to all awards:

6

	<u>3 Months ended March 31,</u>	
	<u>2004</u>	<u>2003</u>
Reported net loss attributable to common stockholders	\$ (5,991,000)	\$ (1,575,000)

(3) Stock-based Compensation

Edgar Filing: AXONYX INC - Form 10-Q

	3 Months ended March 31,	
Stock-based employee compensation included in net loss	145,000	
Stock-based employee compensation determined under the fair value based method	(791,000)	(3,327,000)
Minority interest in stock-based employee compensation determined under the fair value based method	6,000	
Pro forma net loss attributable to common stockholders	\$ (6,631,000)	\$ (4,902,000)
Loss per common share attributable to common stockholders (basic and diluted):		
As reported	\$ (0.13)	\$ (0.07)
Pro forma	\$ (0.15)	\$ (0.21)

(4) Private Placement

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

(5) Operating Segments

The Company is organized into two reportable segments: Axonyx and OXIS. OXIS then has two reportable segments: health products and therapeutic development. The two OXIS segments have different strategic goals and have been managed separately since 1997. The health products segment manufactures and sells diagnostic products, medical instruments, pharmaceutical forms of SOD and other fine chemicals. The therapeutic development segment operates a drug discovery business focused on development of new drugs to treat diseases associated with tissue damage from free radicals and reactive oxygen species.

During the quarter ended March 31, 2004, OXIS general corporate expenses were allocated 80% to the health products segment and 20% to the therapeutic development segment. OXIS general corporate expenses were allocated equally to the health products and therapeutic development segment in 2003.

The following table presents information about the Company's three operating segments:

	Axonyx Inc.	OXIS Health Products	OXIS Therapeutic Development	Total
<i>Quarter ended March 31, 2004</i>				
Revenue including minority interest		\$ 478,000		\$ 478,000
Segment loss	\$ (5,704,000)	(216,000)	\$ (71,000)	(5,991,000)
Segment assets including minority interest at March 31, 2004	87,926,000	1,190,000	778,000	89,894,000

(5) Operating Segments

Edgar Filing: AXONYX INC - Form 10-Q

	Axonyx Inc.	OXIS Health Products	OXIS Therapeutic Development	Total
Segment assets at March 31, 2003	\$ (1,575,000)			\$ (1,575,000)
Segment liabilities at March 31, 2003	5,758,000			5,758,000

(6) Subsequent Event

On May 3, 2004, the Company has entered into definitive agreements with new institutional investors for a private placement of \$20 million of securities through the sale of 3,076,923 shares of common stock at \$6.50 per share. This placement also involved the acquisition by the investor group and a financial advisor of the Company of five-year warrants to purchase an additional 953,846 shares of the Company's stock at an exercise price of \$8.50 per share. The Company will file a registration statement on Form S-3 with the SEC for the resale of common stock within 30 days.

8

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

THIS QUARTERLY REPORT ON FORM 10-Q CONTAINS FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT OF 1933, AS AMENDED, AND SECTION 21E OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. ALL STATEMENTS, OTHER THAN STATEMENTS OF HISTORICAL FACTS, INCLUDED IN OR INCORPORATED BY REFERENCE INTO THIS FORM 10-Q 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 CERTAIN RISKS, UNCERTAINTIES AND ASSUMPTIONS INCLUDING AMONG OTHERS, THE RISK THAT OUR CLINICAL TRIALS WILL NOT PROVE SUCCESSFUL, THAT WE WILL NOT BE ABLE TO OBTAIN FINANCING TO COMPLETE ANY FUTURE TRIALS, THAT THE FDA WILL NOT GRANT MARKETING APPROVAL FOR PHENSERINE OR THAT, IF APPROVED, PHENSERINE WILL NOT PROVE COMPETITIVE IN THE MARKETS. THESE RISKS AND OTHERS ARE MORE FULLY DESCRIBED IN OUR REPORT ON THIS FORM 10-Q AND IN OUR OTHER PUBLIC FILINGS, INCLUDING OUR FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2003. 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 INCLUDED IN SUCH FORWARD-LOOKING STATEMENTS ARE REASONABLE, WE CANNOT GIVE ANY ASSURANCES THAT THESE EXPECTATIONS WILL PROVE TO BE CORRECT. WE UNDERTAKE NO OBLIGATION TO PUBLICLY RELEASE THE RESULT OF ANY REVISIONS TO SUCH FORWARD-LOOKING STATEMENTS THAT MAY BE MADE TO REFLECT EVENTS OR CIRCUMSTANCES AFTER THE DATE HEREOF OR TO REFLECT THE OCCURRENCE OF UNANTICIPATED EVENTS.

We 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 pre-clinical and clinical development towards regulatory approval. We have acquired worldwide exclusive patent rights to three main classes of therapeutic compounds designed for the treatment of Alzheimer's disease (AD), Mild Cognitive Impairment, and related diseases. We have acquired patent rights to a class of potential therapeutic compounds designed for the treatment of prion related diseases, which are degenerative diseases of the brain that are thought to be caused by an infectious form of a protein called a prion. Prions, unlike viruses, bacteria and fungi, have no DNA and consist only of protein. Such diseases include Creutzfeldt Jakob Disease, new variant in humans, Bovine Spongiform Encephalopathy (BSE or Mad Cow Disease) in cows, and Scrapies disease in sheep. We have licensed these patent rights separately from New York University and from the National Institutes of Health/National Institute on Aging (via a sublicense). We also have co-inventorship rights to a patent application regarding a therapeutic compound named Posiphen designed for the treatment of Alzheimer's disease.

We out-source all of our pre-clinical and clinical research and development, utilizing contract research organizations, or CROs, and sponsored research arrangements. We have contracted with several CROs to undertake the pre-clinical and clinical development of Phenserine. We have entered into a License Agreement with Applied Research Systems ARS Holding N.V.

(6) Subsequent Event

(ARS), a subsidiary of Serono International, S.A. (Serono), a Swiss biopharmaceutical company, under which ARS has the rights to conduct research and development on certain of our licensed technologies. We received an up-front fee and a milestone payment, and may receive future milestone payments and royalties, under the License Agreement. We do not currently maintain any laboratory or research premises.

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

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

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

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

The AD targeted approaches include:

- 1) Phenserine, an inhibitor of acetylcholinesterase and the beta-amyloid precursor protein, our lead drug candidate, and Tolserine, another follow-on acetylcholinesterase inhibitor;

- 2) a butyrylcholinesterase inhibitor which will be chosen from a series of selectively acting compounds;
- 3) Posiphen, a compound that decreases the formation of beta-amyloid precursor protein;
- 4) through our sublicense with ARS, a subsidiary of Serono, which is described in greater detail below, compounds called Amyloid Inhibitory Peptides (AIPs) which may prevent and reverse the formation of amyloid plaques in AD.

On May 2, 2000, ARS, a subsidiary of Serono, exercised its right to license certain of our patent rights under the Development Agreement and Right to License signed with us in May of 1999. Under that agreement, ARS paid us a \$250,000 non-refundable fee for the right to license. Pursuant to the resulting License Agreement, which became effective on September 15, 2000, ARS acquired exclusive worldwide patent rights to our AIP and Prion Inhibitory Peptide technologies, called the Licensed Products. In conjunction with the signing of the License Agreement with ARS, we generated \$1.5 million of revenue in the form of an up-front license fee. We received a milestone payment of \$1 million in April 2003 from ARS in relation to the initiation of a Phase I clinical trial with a licensed AIP compound. We may generate additional revenues from ARS if they reach certain development milestones concerning the licensed compounds or other products and related intellectual property, although additional milestone payments did not occur in fiscal year 2003. The Company could receive milestone payments from ARS in an aggregate amount of \$13 million if the Licensed Product involved is a patented product covered by the sub-licensed patents and patent applications and it achieves certain developmental milestones up through health registration approval. The amount of aggregate milestone payments through health registration approval would be \$7 million if the Licensed Product involved was developed by Serono during the one year term of the Development Agreement we entered into with ARS in May 1999. We cannot assure you that licensed compounds or products will reach any particular stage of development requiring a milestone payment, that licensed compounds or products will ever reach the market and give rise to royalty payments, or that additional revenues from patent licensing will be generated or that Serono will continue with any research and development activities.

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

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

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

We have incurred negative cash flows from operations since the inception of the Company in 1997. Our net losses for the three fiscal years ended 2001, 2002, and 2003 were \$8,144,000, \$6,256,000 and \$8,106,000 respectively. As of March 31, 2004, we had an accumulated deficit of \$39,719,000 and our operating losses are continuing. Except of OXIS, we have no products available for sale and we do not expect to have any products commercially available for several years, if at all.

On January 15, 2004, we entered into agreements to acquire approximately 53% of the outstanding voting stock of OXIS is a biopharmaceutical/diagnostic company engaged in the development of research diagnostics, nutraceuticals and therapeutics in the field of oxidative stress. Under the terms of separate agreements entered into with several holders of OXIS common stock, we acquired an aggregate of approximately 14 million shares of OXIS stock, in consideration for our issuance of an aggregate of approximately 1.6 million shares of our unregistered common stock. We filed a registration statement on Form S-3 to register the shares of Axonyx common stock that were issued in the exchange. Marvin S. Hausman, M.D., our Chairman and Chief Executive Officer, owns 1,161,532 shares of OXIS common stock, representing approximately 4% of OXIS's voting stock.

Edgar Filing: AXONYX INC - Form 10-Q

Dr. Hausman's shares of OXIS common stock were not subject to this exchange for our common stock.

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

RESULTS OF OPERATIONS

Revenues

The Company's revenues for the quarters ended March 31, 2004 and 2003 were derived from its majority owned subsidiary, OXIS, as follows:

	<u>2004</u>
Research assays	\$ 456,000
Fine Chemicals	22,000
	<u>\$ 478,000</u>

Costs of Sales

The Company's costs of sales were entirely related to its majority owned subsidiary, OXIS. The percentage of cost of sales for the first quarter of 2004 was 56%.

Research and Development

Research and development expenses for the quarter ending March 31, 2004 were \$4,053,000 compared to \$1,027,000 for the first quarter of 2003. The increase is primarily attributable to the ongoing Phase IIB and Phase III pivotal trials underway in Europe. These trials commenced in June 2003. Additionally, preclinical studies in carcinogenicity and Absorption, Distribution, Metabolism and Excretion (ADME) increased by \$490,000 from the same quarter in 2003.

Sales, General and Administrative

Total sales, general and administrative expenses for the first quarter of 2004 were \$2,371,000, compared to \$573,000 in the first quarter of 2003. Non cash charges relating to stock and options was \$1,116,000 compared to \$77,000 in the quarter ended March 31, 2003. \$495,000 of sales, general and administrative expenses relate to OXIS.

Other Income (Expense)

Interest income for the quarter ending March 31, 2004 was \$185,000 as compared to \$22,000 for the first quarter of 2003. The increase reflects the higher cash and cash equivalent balances in the first quarter of 2004.

Foreign exchange for the first quarter of 2004 was a loss of \$71,000 compared to a foreign exchange gain of \$3,000 for the first quarter of 2003. The loss reflects the increased transactions in Euro denominated currency and the valuation changes between the Euro and the U.S. dollar.

Financing fees and interest expense reflect the cost of borrowing incurred by OXIS in obtaining temporary short term financing.

Net Loss

The Company experienced a loss in the first quarter of 2004 of \$5,991,000 (\$0.13 per share-basic and diluted) compared to a net loss of \$1,575,000 (\$0.07 per share-basic and diluted) net loss for the first quarter of 2003. The increase in the net loss is primarily due to the expense of the ongoing Phase IIB and Phase III clinical trials for Phenserine, an increase in the non-cash stock and option charges and our share of the net loss of OXIS.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2004, we had \$80,640,000 in cash and cash equivalents, and \$77,084,000 in working capital. We do not have any available lines of credit. Since inception we have financed our operations from private placements of equity securities, the exercise of common stock purchase warrants, license fees, interest income and loans from a shareholder.

Net cash used in operating activities for the quarter ended March 31, 2004 was \$4,029,000 resulting from a net loss of \$5,991,000, offset in part by an increase in accounts payable and accrued expenses of \$1,052,000, and stock and option based compensation of \$1,176,000 and depreciation expense of \$165,000. Net cash used in operating activities for the quarter ended March 31, 2003 was \$2,311,000 resulting from a net loss of \$1,575,000 and a decrease in accounts payable and accrued expenses of \$758,000.

Net cash used in investing activities was \$53,000 for the quarter ended March 31, 2004 primarily from the costs related to the acquisition of OXIS.

Net cash from financing activities for the quarter ended March 31, 2004 was \$55,228,000. In January we received net proceeds of \$46,394,000 from a private placement of \$50,000,000 of securities through the sale of 9,650,183 shares of common stock and warrants. Additionally, we received \$8,715,000 during the quarter from the exercise of stock options and warrants and \$119,000 from a bridge loan at the OXIS subsidiary. Net cash from financing activities was \$4,868,000 for the quarter ended March 31, 2003 from the collection of stock subscriptions receivable held in escrow.

13

We currently have contracts with JSW Research of Austria, to undertake the ongoing Phenserine Phase IIB and Phase III clinical trials. We also have contracts with other CROs to provide services relating to Phenserine research and development activities including completing pre-clinical tests on the final drug formulation of Phenserine, undertaking carcinogenicity studies, bio-assays of blood plasma samples, and finalizing drug stability studies. We are currently finalizing a contract with a large CRO to conduct a second pivotal cognition Phase III trial for Phenserine. This contract is expected to be in the range of \$20 million, depending upon the number of patients to be included in the trial. It is expected to commence mid 2004 and run for 18 to 24 months. Finally, under our Research Agreement we are funding a two year research program at the laboratory of Dr. David Small at Monash University in Australia concerning an assay method that is designed to screen potential drug compounds for Alzheimer's disease that have an effect on beta-amyloid. This project is anticipated to cost approximately \$75,000 in 2003, and an additional \$75,000 in 2004. Under our Research and License Agreement with New York University, we must pay minimum annual royalty payments of \$150,000 per year beginning in 2004 through the expiration or termination of that agreement. Our current real estate leases are all on a short-term basis.

We plan to finance our needs principally from the following:

- our existing capital resources and interest earned on that capital;
- future private placement financing or other equity financings..

We believe that we have sufficient capital resources to finance our plan of operation for at least the next twenty-four months. However, as this is a forward-looking statement, and there may be changes that could consume available resources significantly before such time. Our long term capital requirements and the adequacy of our available funds will depend on many factors, including the eventual contract costs of undertaking the Phenserine Phase III clinical trials, regulatory delays, patent costs for filing, prosecuting, maintaining and defending our patent rights, among others.

We are regularly seeking potential equity financing, sub-licensing and other collaborative arrangements that may generate additional capital for us if the FDA requires us to enroll more patients or to conduct one or more additional pivotal Phase III clinical trials. We cannot assure you that we will generate sufficient additional capital or revenues, if any, to fund our operations beyond the 24 month period ending May 31, 2006, that any future equity financings will be successful, or that other potential financings through bank borrowings, debt or equity offerings, or otherwise, will be available on acceptable terms or at all.

The Company's liquidity and capital resources position is currently adequate to support its own development plans for at least the next 24 months. However, the liquidity and capital resource position of the Company's majority owned subsidiary, OXIS, standing alone, is not adequate to support its ongoing operations without additional capital. OXIS' working capital deficit increased during the first quarter of 2004 to \$50,000, from a deficit of \$36,000 at December 31, 2003 and cash and cash equivalent decreased to \$308,000 at March 31, 2004 from \$372,000 at December 31, 2003.

OXIS expects to incur operating losses for the foreseeable future. There can be no assurance that OXIS will ever achieve profitable operations. The report of the OXIS' independent auditors on the company's financial statements for the period ended December 31, 2003, includes an explanatory paragraph referring to OXIS' ability to continue as a going concern.

OXIS needs to raise additional capital for continuing operations of the health products segment and to complete its contemplated drug development programs and no assurances can be given that OXIS will be able to raise such capital on favorable terms. As the majority stockholder and an interested person under Delaware law, the Company is limited in the ways in which it can provide financial assistance to OXIS. The unavailability of additional capital could cause OXIS to cease or curtail its operations and/or delay or prevent the development and marketing of the Company's existing and potential products.

Critical Accounting Policies and Estimates.

This discussion and analysis of our financial condition and results of operations are based on our financial statements that have been prepared under accounting principles generally accepted in the United States of America. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could materially differ from those estimates. We have disclosed all significant accounting policies in note B to the financial statements included in our Form 10-K for the year ended December 31, 2003. Our critical accounting policies are:

Inventories: Inventories are stated at the lower of cost or market. Cost has been determined by using the first-in, first-out method.

Revenue recognition: We defer recognition of revenue from fees received in advance unless they represent the culmination of a separate earnings process. Such deferred fees are recognized as revenue over the term of the arrangement as they are earned, in accordance with the agreement. License fees represent the culmination of a separate earnings process if they are sold separately without obligating us to perform research and development activities or other services. Rights to license fees are recognized over the term of the arrangement. Nonrefundable, non-creditable license fees that represent the culmination of a separate earnings process are recognized upon execution of the license agreement. Revenue from the achievement of milestone events stipulated in the agreements will be recognized when the milestone is achieved. Royalties will be recognized as revenue when the amounts earned become fixed and determinable.

OXIS manufactures, or has manufactured on a contract basis, products that are sold to customers. OXIS recognizes product sales upon shipment of the product to the customer. OXIS also develops and acquires technology that is used in its operations or sold, licensed or assigned to third parties. OXIS recognizes revenue upon the sale or assignment of technology to third parties.

Research, development costs: Research and development costs are expensed as incurred.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We have foreign currency accounts that are exposed to currency exchange risk. These foreign currency accounts have been utilized to fund the operations of our wholly owned subsidiary, Axonyx Europe, based in the Netherlands. We had a net foreign exchange loss of \$71,000 for the quarter ended March 31, 2004 and a gain of \$3,000 for the quarter ended March 31, 2003. If the foreign currency rates were to fluctuate by 10% from rates at March 31, 2004 and 2003, the effect on our financial statements would not be material. However, there can be no assurance there will not be a material impact in the future. During 2003, we adopted a policy to limit the purchase of foreign currencies to the amounts necessary to cover firm contractual commitments in foreign currencies for the forward six months. However, as long as we continue to fund our foreign operations, we will be exposed to some currency exchange risks. The majority of our ongoing clinical trials are being conducted in Europe.

We consider our investments in money market accounts, short term commercial paper and time deposits as cash and cash equivalents. The carrying values of these investments approximate fair value because of the short maturities (three months or less) of these instruments and accounts. Therefore, changes in the market's interest rates do not affect the value of the investments as recorded by us.

We do not enter into or trade derivatives or other financial instruments or conduct any hedging activities.

Item 4. 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 Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this quarterly report on Form 10-Q. 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, 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.

Changes in Internal Controls

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-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.

PART II OTHER INFORMATION

Changes in Internal Controls

Item 6. Exhibits and Reports on Form 8-K

(a) *Exhibits*

- 10(a) * Securities Purchase Agreement dated as of January 8, 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 January 12, 2004);
- 10(b) * 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);
- 10(c) * 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(d) * 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(e) * Change of Control Agreement dated as of March 30, 2004 between Axonyx Inc. 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(f) * Change of Control Agreement dated as of March 30, 2004 between Axonyx Inc. 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(g) * Securities Purchase Agreement dated as of May 3, 2004 between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.1 in the current report on Form 8-K previously filed by Axonyx Inc. on May 5, 2004);
- 10(h) * 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);

18

- 31(a) Rule 13a-14(a) Certification by Chief Executive Officer;
- 31(b) Rule 13a-14(a) Certification by Chief Financial Officer;
- 32(a) Section 1350 Certification by Chief Executive Officer;
- 32(b) Section 1350 Certification by Chief Financial Officer.

* Previously filed

(b) *Reports on Form 8-K*

- 1. We filed a Current Report on Form 8-K (item 5) with the Securities and Exchange Commission on January 12, 2004, reporting our press release, Axonyx Announces \$50 Million Private Placement of Common Stock and Warrants .

Edgar Filing: AXONYX INC - Form 10-Q

2. We filed a Current Report on Form 8-K (items 2 and 7) with the Securities and Exchange Commission on January 20, 2004, reporting our press release, Axonyx Inc. today announced that it has entered into agreements to acquire approximately 53% of the outstanding voting stock of OXIS . We filed a Form 8-K/A amending such form on March 30, 2004, to include Item 7(a) Financial Statements of Business Acquired and Item 7(b) Pro Forma Financial Information.
3. We filed a Current Report on Form 8-K (item 5) with the Securities and Exchange Commission on May 5, 2004, reporting our press release, Axonyx Announces \$20 million Private Placement of Common Stock and Warrants .

19

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated May 14, 2004.

AXONYX INC.

By: /s/ Marvin S. Hausman, M.D.

Marvin S. Hausman, M.D.
Chairman and Chief Executive Officer

By: /s/ S. Colin Neill

S. Colin Neill
Chief Financial Officer,
Secretary and Treasurer
(Principal Financial and Accounting Officer)

20

SIGNATURES

17