AXONYX INC
Form 10-Q
November 10, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

|X| QUARTERLY REPORT PURSUANT TO SECTION 12 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2004

or

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

Commission file number 000-25571

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

Nevada	**86-0883978**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Id. No.)

500 Seventh Avenue, 10th Floor
New York, New York 10018
(Address of principal executive offices)

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

Indicate by 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 |X| No |_|.

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

As of November 10, 2004 the Registrant had outstanding 53,039,155 shares of its $.001 par value Common Stock.

AXONYX INC.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

AXONYX INC.

Condensed Consolidated Balance Sheets

ASSETS	**September 30, 2004**	**December 31, 2003**
	(unaudited)	
Current Assets:		
Cash and cash equivalents	$ 87,664,000	$ 28,780,000
Accounts receivable	370,000	
Inventories	349,000	
Other current assets	206,000	
Total current assets	88,589,000	28,780,000
Equipment, net	88,000	24,000
Technology for developed products, net	6,996,000	
Patents and patents pending, net	969,000	
Security deposit	18,000	11,000
	$ 96,660,000	$ 28,815,000
LIABILITIES		
Current liabilities:		
Accounts payable	$ 3,036,000	$ 1,284,000
Accrued expenses	2,524,000	880,000
Note payable	160,000	
Convertible bridge loans	404,000	
Total liabilities	6,124,000	2,164,000
STOCKHOLDERS EQUITY		
Preferred stock - $.001 par value, 15,000,000 shares authorized; none issued		
Common Stock - $.001 par value, 150,000,000 and 75,000,000 shares authorized; as of 2004 and 2003 respectively; 51,706,222 and 33,919,948 shares issued and outstanding in 2004 and 2003 respectively	51,000	34,000
Additional paid-in capital	144,238,000	60,345,000
Unearned compensation - stock options	(177,000)	

ASSETS	**September 30, 2004**	**December 31, 2003**
Accumulated comprehensive loss	(32,000)	
Accumulated deficit	(53,544,000)	(33,728,000)
Total stockholders equity	90,536,000	26,651,000
Total liabilities and stockholders equity	$ 96,660,000	$ 28,815,000

See notes to condensed consolidated financial statements.

AXONYX INC.

Condensed Consolidated Statements of Operations
(unaudited)

	Three months ended Sept 30, 2004	2003	NIne months ended September 30, 2004	2003
Revenue				
Licensing	$ 450,000	$	$ 450,000	$ 1,000,000
Product sales	504,000		1,415,000	
Total revenue	954,000		1,865,000	1,000,000
Cost of product sales	282,000		786,000	
Gross profit	672,000		1,079,000	1,000,000
Costs and expenses:				
Research and development	6,054,000	$ 986,000	15,888,000	3,262,000
Sales, general and administrative	1,540,000	844,000	6,038,000	2,434,000
	7,594,000	1,830,000	21,926,000	5,696,000
Loss from operations	(6,922,000)	(1,830,000)	(20,847,000)	(4,696,000)
Other income (expense)				
Interest income	379,000	22,000	805,000	59,000
Foreign exchange	(3,000)	5,000	(40,000)	13,000
Gain on issuance of subsidiary stock	16,000		71,000	
Financing fees	(164,000)		(464,000)	
Interest expense	(13,000)		(38,000)	
Net loss before minority interest in subsidiary	(6,707,000)	(1,803,000)	(20,513,000)	(4,624,000)
Minority interest in loss of subsidiary	14,000		697,000	
Net loss	(6,693,000)	(1,803,000)	(19,816,000)	(4,624,000)
Comprehensive loss				
Foreign currency translation adjustment	2,000		(32,000)	
Comprehensive loss	$ (6,691,000)	$ (1,803,000)	$ (19,848,000)	$ (4,624,000)
Net loss per common share	$ (0.13)	$ (0.07)	$ (0.40)	$ (0.18)
Weighted average shares-basic and diluted	51,701,443	27,398,419	48,974,854	25,107,598

See notes to condensed consolidated financial statements.

AXONYX INC.

Condensed Consolidated Statements of Changes in Stockholders Equity
(unaudited)

	Common Stock						
	Number of Shares	Amount	Additional Paid-in Capital	Unearned Compensation Stock Options	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders Equity
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	12,727,106	13,000	64,745,000				64,758,000
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			1,504,000				1,504,000
Issuance of common stock options			387,000	(387,000)			
Exercise of common stock warrants and options	3,441,107	3,000	9,064,000				9,067,000
Amortization				210,000			210,000
Foreign currency translation adjustment						(32,000)	(32,000)
Net loss					(19,816,000)		(19,816,000)
Balance - September 30, 2004	51,706,222	$ 51,000	$ 144,238,000	$ (177,000)	$ (53,544,000)	$ (32,000)	$ 90,536,000

See notes to condensed consolidated financial statements.

AXONYX INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Nine months ended September 30, 2004	2003
Cash flows from operating activities:		
Net Loss	$ (19,816,000)	$ (4,624,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	657,000	12,000
Amortization of deferred financing costs	404,000	
Minority interest in net loss of subsidiary	(697,000)	
Compensation related to common stock issued for services	47,000	213,000
Compensation related to options and warrants issued for services	1,714,000	310,000
Gain on issuance of subsidiary stock	(71,000)	
Changes in:		
Accounts receivable	(103,000)	
Inventory	(54,000)	
Other current assets	10,000	(38,000)
Other assets	25,000	44,000
Accounts payable	1,202,000	(461,000)
Accrued expenses and other	1,409,000	(250,000)
Accrued stock based compensation	(121,000)	258,000
Net cash used in operating activities	(15,394,000)	(4,536,000)
Cash flows from investing activities:		
Cash acquired in connection with Oxis acquistion	714,000	
Costs related to Oxis acquistion	(52,000)	
Additions to patents	(240,000)	
Purchase of equipment	(49,000)	
Net cash provided from investing activities	373,000	
Cash flows from financing activities		
Net proceeds from issuance of common stock and warrants	64,758,000	26,661,000
Net proceeds from exercise of common stock options and warrants	9,067,000	
Net proceeds from exercise of common stock options in Oxis	80,000	
Collection of stock subscriptions receivable and cash held in escrow		4,868,000
Net cash provided from financing activities	73,905,000	31,529,000
Net increase in cash and cash equivalents	58,884,000	26,993,000
Cash and cash equivalents at beginning of period	28,780,000	3,021,000
Cash and cash equivalents at end of period	$ 87,664,000	$ 30,014,000
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	

See notes to condensed consolidated financial statements.

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 September 30, 2004 and the results of operations for the quarterly and nine month 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 acquired.

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 a 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
	$ 8,246,000

(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 carryfoward 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 and nine months ended September 30, 2004 and 2003.

	Three months ended Sept. 30,		Nine months ended Sept. 30,	
	2004	2003	2004	2003
Total revenues	$ 954,000	$ 560,000	$ 1,954,000	$ 2,770,000
Net loss including minority interest in subsidiary	(6,707,000)	(2,135,000)	(20,630,000)	(5,760,000)
Net loss	(6,693,000)	(2,067,000)	(19,893,000)	(5,492,000)
Basic and diluted net loss per common share	(0.13)	(0.07)	(0.40)	(0.21)

(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:

	Three months ended Sept. 30,		Nine months ended Sept. 30,	
	2004	2003	2004	2003
Net loss	$ (6,693,000)	$ (1,803,000)	$ (19,816,000)	$ (4,624,000)
Stock-based employee compensation included in net loss	33,000		210,000	
Stock-based employee compensation determined under the fair value based method	(636,000)	(592,000)	(1,879,000)	(2,313,000)
Minority interest in stock-based employee compensation determined under the fair value based method	149,000		214,000	
Pro forma net loss	$ (7,147,000)	$ (2,395,000)	$ (21,271,000)	$ (6,937,000)

	Three months ended Sept. 30,		Nine months ended Sept. 30,	
Loss per common share (basic and diluted):				
As reported	$ (0.13)	$ (0.07)	$ (0.40)	$ (0.18)
Pro forma	$ (0.14)	$ (0.09)	$ (0.44)	$ (0.28)

(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.

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

(5) Operating Segments

The Company is organized into two reportable segments: Axonyx and OXIS. While OXIS has historically been organized into two reportable segments (health products and therapeutic development), Oxis currently manages its operations in one segment in order to better monitor and manage its basic business: the development of research diagnostics, nutraceutical and therapeutic products.

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

	Axonyx Inc.	Oxis Int l Inc.	Total
Quarter ended September 30, 2004			
Revenue including minority interest		$ 954,000	$ 954,000
Segment loss	$ (6,466,000)	$ (227,000)	$ (6,693,000)
Quarter ended September 30, 2003			
Revenue including minority interest			
Segment loss	$ (1,803,000)		$ (1,803,000)
Nine months ended September 30, 2004			
Revenue including minority interest		$ 1,865,000	$ 1,865,000
Segment loss	$ (18,226,000)	$ (1,590,000)	$ (19,816,000)
Segment assets including minority interest at September 30, 2004	$ 87,002,000	$ 9,658,000	$ 96,660,000
Nine months ended September 30, 2003			
Revenue including minority interest	$ 1,000,000		$ 1,000,000
Segment loss	$ (4,624,000)		$ (4,624,000)
Segment assets at September 30, 2003	$ 30,091,000		$ 30,091,000

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(6) Related Party Transaction

In June 2004, Axonyx Inc., which holds a controlling interest in OXIS International, Inc., loaned OXIS $1.2 million, which will be due and payable in one year or until a qualified financing occurs (whichever is earlier). Interest on this loan accrues at 7% per annum and is payable quarterly. This loan is partially secured by certain assets of OXIS. The loan, in the form of a one-year secured note, will be used to continue the advancement of OXIS oxidative stress programs and other working capital purposes.

(7) Developments with SERONO International SA

In July 2004, Axonyx and Serono International, S.A. (NYSE: SRA) signed a non-binding Memorandum of Understanding (MOU) for the research and joint development of therapeutic compounds (including the Amyloid Inhibitory and Prion Inhibitory Peptides described in more detail in Item 2 below) and diagnostic technologies in the field of protein mis-folding disorders such as Parkinson s Disease, Down s Syndrome, Diabetic disorders, Lou Gehrig s Disease, Alzheimer s Disease, Transmissible Spongioform Encephalopathies (TSE s) i.e. Mad Cow Disease (BSE) and Creutzfeldt Jakob Disease new variant (CJDnv).

The MOU proposes that Serono and Axonyx each will transfer certain technologies and proprietary rights to a public entity they will jointly acquire, including technologies previously licensed by Axonyx to Serono, as well as additional related intellectual property and expertise subsequently developed by Serono. In addition to contributing specifically enumerated technologies to the new venture, Axonyx will invest $5 million. The parties anticipate that some time after its formation, the new venture will then separately raise additional capital in the public markets to fund its research and development activities. The ultimate objective is to form a company that will specialize in the development of therapeutic compounds for the diagnosis and treatment of protein mis-folding disorders.

Under the terms of the MOU, the Chief Operating Officer of the new venture will be Dr. Silvano Fumero, formerly the head of research and development at Serono, and the parties anticipate that the new venture will enter into a collaborative research agreement with Creabilis Therapeutics srl, a private company controlled by Dr. Fumero. The Chief Scientific Officer will be Dr. Claudio Soto, who was responsible for the initial discovery and development of the key technology that will be contributed to the joint venture. Axonyx will have a majority of the voting stock of the new venture and initially will designate a majority of its directors.

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

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

Following the signing of the MOU, the parties have been negotiating the terms of definitive agreements. Although there is no assurance that a closing will occur, the parties hope to be able to finalize documents and consummate the transactions in the near future. When the agreements contemplated under the MOU are finalized, the revenues and milestone payments described in earlier SEC filings under the original licensing agreements with SERONO will not occur.

(8) Oxis International License Agreement

On September 28, 2004, Oxis International (Oxis), of which the Company owns 53%, and HaptoGuard Inc. (HaptoGuard) entered into a license agreement relating to Oxis proprietary compound BXT 51072 and related compounds. Under the agreement, HaptoGuard has exclusive worldwide rights to develop, manufacture and market BXT-51072 and related compounds from the Oxis library of such antioxidant compounds. Further, HaptoGuard is responsible for worldwide product development programs with respect to licensed compounds. HaptoGuard has paid Oxis an upfront license fee of $300,000, and an additional $150,000 in upfront license fees remains payable by HaptoGuard. The agreement provides that HaptoGuard must pay royalties to Oxis, as well as additional fees for the achievement of development milestones in excess of $21 million if all milestones are met and regulatory approvals are granted. However, there can be no assurances that royalty payments will result or that milestone payments will be realized.

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 COMPETITVE 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.

Axonyx s primary corporate business objective isto successfully establish Axonyx as a later-stage, biopharmaceutical product development company specialized in the CNS area, with a focus on commercializing effective therapeutics for neurodegenerative diseases, as well as for other medical conditions associated with cognitive impairment. We are engaged in the business of acquiring and developing 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. (ARS), a subsidiary of Serono International, S.A. (Serono), a Swiss biopharmaceutical company, under which ARS has the rights to conduct research and development on certain of our licensed technologies. We received an up-front fee and a milestone payment, and may receive future milestone payments and royalties, under the License Agreement. We are currently renegotiating our arrangement with Serono as discussed in note (7) to the condensed consolidated financial statements contained elsewhere herein. We do not currently maintain any laboratory or research premises.

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

In early June 2003, we initiated a Phase IIb clinical trial designed to evaluate the effects of Phenserine on the levels of beta-amyloid precursor protein and beta amyloid in the plasma and cerebrospinal fluid of AD patients. The beta amyloid protein is one of more than a dozen types of amyloid proteins found in the body. Beta amyloid is derived from the beta-amyloid precursor protein normally present in the brain of healthy individuals in small quantities. Beta-amyloid, derived from the beta-amyloid precursor protein, is over-produced in AD and Down s Syndrome. In AD, the beta-amyloid protein undergoes a conformational change, aggregates and is deposited as insoluble fibrils in amyloid plaques in the brain. The beta-amyloid precursor protein is present in the cell wall of numerous cells within the body including nerve cells of the brain. Beta-amyloid protein is derived from this larger protein. In late June 2003, we also initiated a Phase III potentially pivotal clinical trial to further examine the safety and efficacy of Phenserine on AD patients. In June 2004, we completed enrollment in the 1st Phase III trial and initiated a 2nd Phase III trial with 450 patients. We initiated a third Phase III cognition trial, also with 450 patients, in September 2004.

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

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

The AD targeted approaches include:

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. Previous SEC filings described in detail the additional revenues and milestone payments that the company would receive depending on the development progress made by SERONO with the licensed technologies. As described in the footnote number 7 to the financial statements in this Form 10Q under the heading Developments with SERONO International SA we have signed a non-binding memorandum of understanding for the research and join development of therapeutic compounds, including the licensed technologies. The intent of the company and SERONO is to shortly complete this agreement and establish a new venture to develop the technologies. Under this scenario the revenues and milestone payments previously detailed would not occur.

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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 September 2005. It is anticipated that the Axonyx rights to the assay may be transferred to the Serono-Axonyx public entity as described in note (7) to the condensed consolidated financial statements contained elsewhere herein.

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

We have incurred net losses and negative cash flows from operations since the inception of the Company in 1997. As of September 30, 2004, we had an accumulated deficit of $53,544,000 including a net loss of $19,816,000 for the nine months ended September 30, 2004, and our operating losses are expected to continue. Except for OXIS, we have no products available for sale and we do not expect to have any products commercially available for several years, if at all.

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

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

RESULTS OF OPERATIONS

Revenues

The Company had revenue of $954,000 and $-0- for the three months ended September 30, 2004 and 2003 respectively. The Company had revenue of $1,865,000 and $1,000,000 for the nine months ended September 30, 2004 and 2003 respectively. Revenue in 2004 was derived from the sale of research assays and fine chemicals at Oxis and a licensing agreement at Oxis for $450,000. In April 2003, Axonyx received a milestone payment of $1,000,000 from Serono International S.A. (Serono) under the terms of a license agreement for beta-sheet breaker technology that was signed in September 2000. The milestone payment was triggered when Serono initiated a Phase I clinical trial with a beta-sheet breaker peptide for the potential treatment of Alzheimer s disease.

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 both the quarter and nine months ended September 30, 2004 was 56%.

Research and Development

Research and development expenses were $6,054,000 and $986,000 for the quarters ended September 30, 2004 and 2003, respectively. Research and development expenses were $15,888,000 and $3,262,000 for the nine months ended September 30, 2004 and 2003, respectively. The increase is primarily attributable to the ongoing Phase IIB and Phase III pivotal trials underway in Europe. These trials commenced in June 2003. In June 2004, we have initiated a 2nd Phase III trial and incurred start up costs including the initial investigators meeting. Addditionally, preclinical studies in carcinogenicity and Absorption, Distribution, Metabolism and Excretion (ADME) increased by $2,292,000 from the same nine month period in 2003.

Sales, General and Administrative

Sales, general and administrative expenses were $1,540,000 and $844,000 for the quarters ended September 30, 2004 and 2003, respectively. Sales, general and administrative expenses were $6,038,000 and $2,434,000 for the nine months ended September 30, 2004 and 2003, respectively. Non-cash charges relating to stock option grants to consultants were $1,484,000 compared to $544,000 in the nine months ended September 30, 2004 and 2003, respectively. Professional fees were $1,050,000 compared to $664,000 in the nine months ended September 30, 2004 and 2003, respectively. The increase in professional fees is primarily attributed to acquisition costs, utilization of outside council and patent filings. $2,122,000 of sales, general and administrative expenses relate to OXIS.

Other Income (Expense)

Interest income was $379,000 and $22,000 for the quarters ending September 30, 2004 and 2003, respectively. Interest income was $805,000 and $59,000 for the nine months ended September 30, 2004 and 2003. The increase reflects the higher cash and cash equivalent balances held in 2004 resulting from the cash collected from several private placements occurring in late 2003 and 2004.

Foreign exchange for the nine months ended September 30, 2004 was a loss of $40,000 compared to a foreign exchange gain of $13,000 for the nine months ended September 30, 2003. The loss reflects the increased transactions in Euro denominated currency and the valuation changes

between the Euro and the U.S. dollar.

Gain on issuance of subsidiary stock was $71,000 for the nine months ended September 30, 2004. This gain results from common stock issued in OXIS.

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

Net Loss

The Company experienced net losses of $6,693,000 ($0.13 per share-basic and diluted) and $1,803,000 ($0.07 per share-basic and diluted) for the quarters ended September 30, 2004 and 2003, respectively. The Company experienced net losses of $19,816,000 ($0.40 per share-basic and diluted) and $4,624,000 ($0.18 per share-basic and diluted) for the nine months ended September 30, 2004 and 2003, respectively. The increase in the net loss is primarily due to the expense of the ongoing Phase IIB and Phase III clinical trials for Phenserine, initiation of the 2nd Phase III clinical trial, an increase in the non-cash stock and option charges and our share of the net loss of OXIS.

Comprehensive Loss

The Company reported for the nine months ended September 30, 2004 a $32,000 foreign currency translation adjustment occurring in the OXIS subsidiary.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2004, we had $87,664,000 in cash and cash equivalents, and $82,465,000 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 nine months ended September 30, 2004 was $15,394,000 resulting from a net loss of $19,816,000, offset in part by an increase in accounts payable and accrued expenses of $2,490,000, equity based compensation of $1,761,000 and depreciation and amortization expense of $1,061,000. Net cash used in operating activities for the nine months ended September 30, 2003 was $4,536,000 resulting from a net loss of $4,624,000, equity based compensation of $523,000 and a decrease in accounts payable and accrued expenses of $453,000.

Net cash provided from investing activities was $373,000 for the nine months ended September 30, 2004. $714,000 was acquired in connection with the Oxis acquisition offset in part by costs related to additions to patents, the acquisition of OXIS and office equipment purchases.

Net cash from financing activities for the nine months ended September 30, 2004 was $73,905,000. 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. In May we received net proceeds of $18,364,000 from the private placement of $20,000,000 of securities through the sale of 3,076,923 shares of common stock and warrants. Additionally, we received $9,067,000 during the period from the exercise of stock options and warrants and $80,000 from the exercise of common stock options in OXIS.

Net cash from financing for the nine months ended September 30, 2003 was $31,529,000 of which $4,868,000 was from the collection of stock subscriptions receivable held in escrow from a private placement of shares of common stock and warrants that closed on December 31, 2002. Net cash from financing in June 2003 was $3,243,000. In June 2003, we received aggregate gross proceeds of approximately $2.3 million and issued 919,130 shares of common stock upon the exercise of warrants by fifteen holders of AXC warrants pursuant to a special offer. In June 2003, we raised aggregate gross proceeds of $575,000 through the sale of 230,000 shares of common stock at $2.50 per share in a private

placement with four European accredited investors. Also in June 2003, we received gross proceeds of approximately $345,000 and issued approximately 775,000 shares to holders of AXD warrants who exercised their warrants. In September 2003, we received net proceeds of $23,418,000 from a private placement of common stock and warrants which closed on September 11, 2003.

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 second and third pivotal cognition Phase III trials for Phenserine, each with a target enrollment of 450 patients. This multi-year contract is expected to be in the range of $20 million, depending upon the number of patients to be included in the trial. The studies commenced in 3rd quarter 2004 and are expected to run 24 to 30 months. Finally, under our Research Agreement we are funding a three 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 research project cost $75,000 in 2003, and it is anticipated to cost an additional $75,000 in the 2004 year. 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 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 September 30, 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 nine months of 2004 to $1,313,000, from a deficit of $36,000 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.

Executive Stock Trading Program

In June 2004, the Chairman of the Board and Chief Executive Officer of the Company, Marvin S. Hausman, M.D., adopted a pre-arranged stock trading plan in accordance with guidelines specified by Rule 10b5-1 under the Securities Exchange Act of 1934.

Rule 10b5-1 permits officers and directors of public companies to adopt pre-determined plans for selling specified amounts of stock. The plans may be entered into only when the director or officer is not in possession of material, non-public information and may be used to gradually diversify investment portfolios over a period of time.

Dr. Hausman will only sell shares of stock if the Company s stock price exceeds $6.00 per share. As of November 2, 2004, Dr. Hausman has sold 80,000 shares, with a first trade on September 16, 2004. Under the terms of Dr. Hausman s one-year plan, he may, prior to July 10, 2005, sell, on a pro rated monthly basis, up to an aggregate of 200,000 shares, which represents approximately 6.4% of the total number of shares and currently exercisable warrants and options he currently holds. Dr. Hausman has adopted his stock selling plan for financial planning purposes and to diversify his personal portfolio.

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 sales of the product to the customers.

Oxis recognizes license fee revenue for licenses to intellectual property when earned under the terms of the agreements. Generally, revenue is recognized upon transfer of the license unless Oxis has continuing obligations for which fair value cannot be established, in which case the revenue is recognized over the period of the obligation. If there are extended payment terms, Oxis recognizes license fee revenue as these payments become due. All arrangements with payment terms extending beyond 12 months are not considered to be fixed or determinable. In certain licensing arrangements there is provision for a variable fee as well as a non-refundable minimum amount. In such arrangements, the amount of the non-refundable minimum guarantee is recognized upon transfer of the license unless we have continuing obligations for which fair value cannot be established and the amount of the variable fee in excess of the guaranteed minimum is recognized as revenue when it is fixed and determinable. Oxis recognizes royalty revenue based on reported sales by third party licensees of products containing its materials, software and intellectual property. If there are extended payment terms, royalty revenues are recognized as these payments become due. Non-refundable royalties, for which there are no further performance obligations, are recognized when due under the terms of the agreements.

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

Risks and Uncertainties

The Company s lead compound, Phenserine, is currently undergoing clinical testing in three Phase III trials and a Phase IIb clinical trial. Enrollment in the first Phase III trial was completed in June 2004 and the Company expects to have data from this trial, plus interim analysis data from the Phase IIb trial, available during the first quarter of 2005. Until the trial is unblinded and the results analyzed, there cannot be any assurance that the clinical endpoints in the protocol have been met.

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 $40,000 for the nine months ended September 30, 2004 and a gain of $13,000 for the nine months ended September 30, 2003. If the foreign currency rates were to fluctuate by 10% from rates at September 30, 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
Item 6 Exhibits

Number	Exhibit
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15(d)-14(a), adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15(d)-14(a), adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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 November 10, 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)