TorreyPines Therapeutics, Inc.
Form 10-Q
November 09, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2006

or

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

For the transition period from to .

Commission file number: 000-25571

TORREYPINES THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**86-0883978**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Id. No.)
11085 North Torrey Pines Road, Suite 300, La Jolla, CA	**92037**
(Address of principal executive offices)	(Zip code)

Registrant s telephone number, including area code: **(858-623-5665)**

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 o.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large Accelerated filer o Accelerated Filer x Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x.

As of November 4, 2006, there were 15,670,832 shares of the registrant s $.001 par value Common Stock outstanding.

TorreyPines Therapeutics, Inc. (formerly Axonyx Inc.)

INDEX

PART 1.	FINANCIAL INFORMATION	
Item 1.	Financial Statements	
	Condensed Consolidated Balance Sheets as of September 30, 2006 (unaudited) and December 31, 2005	1
	Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2006 and 2005	2
	Condensed Consolidated Statement of Changes in Stockholders Equity (unaudited) for the nine months ended September 30, 2006	3
	Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2006 and 2005	4
	Notes to Condensed Consolidated Financial Statements	5
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	11
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	15
Item 4.	Controls and Procedures	15
PART II	OTHER INFORMATION	16
Item 1.	Legal Proceedings	16
Item 1A.	Risk Factors	16
Item 4.	Submission of Matters to a Vote of Security Holders	29
Item 6.	Exhibits	30
Signatures		31

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TorreyPines Therapeutics, Inc.
(formerly Axonyx Inc.)
Condensed Consolidated Balance Sheets

	September 30, 2006	December 31, 2005
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,352,000	1,638,000
Investments	45,300,000	56,700,000
Other current assets	208,000	614,000
Total current assets	46,860,000	58,952,000
Property, plant and equipment, net	38,000	49,000
Investment in Oxis	4,089,000	4,917,000
Security and deposits	23,000	124,000
	$ 51,010,000	64,042,000
LIABILITIES		
Current liabilities:		
Accounts payable	$ 2,479,000	4,147,000
Accrued expenses	4,135,000	1,512,000
Total current liabilities	6,614,000	5,659,000
STOCKHOLDERS EQUITY		
Preferred stock - $.001 par value, 15,000,000 shares authorized; none issued		
Common Stock - $.001 par value, 150,000,000 authorized in 2006 and 2005 6,710,090 issued and outstanding	7,000	7,000
Additional paid-in capital	150,801,000	149,513,000
Unearned compensation - stock options		(15,000)
Accumulated deficit	(106,412,000)	(91,122,000)
Total stockholders equity	44,396,000	58,383,000
Total liabilities and stockholders equity	$ 51,010,000	64,042,000

See notes to the condensed consolidated financial statements

1

TorreyPines Therapeutics, Inc.
(formerly Axonyx Inc.)

Condensed Consolidated Statements of Operations
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2006	**2005**	**2006**	**2005**
Revenue				
Product sales	$	$	$	$ 403,000
Cost of product sales				210,000
Gross profit				193,000
Costs and expenses:				
Research and development	1,354,000	5,135,000	6,973,000	21,808,000
General and administrative	884,000	1,018,000	4,437,000	3,894,000
Merger costs	5,346,000		5,346,000	
	7,584,000	6,153,000	16,756,000	25,702,000
Loss from operations	(7,584,000)	(6,153,000)	(16,756,000)	(25,509,000)
Other income (expense)				
Investment income	631,000	586,000	1,963,000	1,716,000
Interest expense				(2,000)
Gain (loss) on issuance of Oxis stock	84,000	2,000	162,000	(318,000)
Equity in loss of Oxis	(210,000)	(108,000)	(625,000)	(255,000)
Foreign exchange	(11,000)	(14,000)	(34,000)	(95,000)
Total other income (expense)	494,000	466,000	1,466,000	1,046,000
Net loss before minority interest in Oxis	(7,090,000)	(5,687,000)	(15,290,000)	(24,463,000)
Outside interest in loss of Oxis				164,000
Net loss	$ (7,090,000)	$ (5,687,000)	$ (15,290,000)	$ (24,299,000)
Net loss per common share - basic and diluted	$ (1.06)	$ (0.85)	$ (2.28)	$ (3.62)
Weighted average shares basic and diluted	**6,710,000**	**6,709,000**	**6,710,000**	**6,708,000**

See notes to the condensed consolidated financial statements

TorreyPines Therapeutics, Inc.
(formerly 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**	**Total Stockholders Equity**
Balance - December 31, 2005	6,710,090	$ 7,000	$ 149,513,000	$ (15,000)	$ (91,122,000)	$ 58,383,000
Issuance of common stock options and warrants for consulting services			18,000			18,000
Issuance of common stock options			1,270,000			1,270,000
Amortization				15,000		15,000
Net loss					(15,290,000)	(15,290,000)
Balance September 30, 2006	6,710,090	$ 7,000	$ 150,801,000	$	$ (106,412,000)	$ 44,396,000

See notes to the condensed consolidated financial statements

TorreyPines Therapeutics, Inc.
(formerly Axonyx Inc.)

Condensed Consolidated Statements of Cash Flows
(unaudited)

	Nine months ended September 30,	
	2006	**2005**
Cash flows from operating activities:		
Net loss	$ (15,290,000)	$ (24,299,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	376,000	423,000
Compensation related to common stock issued for services	1,303,000	319,000
Minority interest in net loss of Oxis		(164,000)
Loss (gain) on issuance of Oxis stock	(162,000)	318,000
Equity in loss of Oxis	625,000	255,000
Changes in:		
Accounts receivable		(105,000)
Inventories		(1,000)
Other current assets	406,000	(91,000)
Other assets	101,000	(6,000)
Accounts payable	(1,668,000)	(2,217,000)
Accrued expenses	2,636,000	1,193,000
Accrued stock based compensation	(13,000)	(353,000)
Net cash used in operating activities	(11,686,000)	(24,728,000)
Cash flows from investing activities:		
Purchase of equipment		(13,000)
Additions to patents		(48,000)
Reduction in cash due to deconsolidation of Oxis		(4,907,000)
Purchases of investments	(14,400,000)	(49,750,000)
Proceeds from sales and maturities of investments	25,800,000	69,450,000
Net cash provided by investing activities	11,400,000	14,732,000
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants		20,000
Collection of stock subscription receivable - Oxis		2,250,000
Net proceeds from exercise of common stock options in Oxis		33,000
Net cash provided by financing activities		2,303,000
Net decrease in cash and cash equivalents	(286,000)	(7,693,000)
Cash and cash equivalents at beginning of period	1,638,000	10,091,000
Cash and cash equivalents at end of period	$ 1,352,000	$ 2,398,000

Supplemental cash flow disclosures		
Interest paid	$	2,000
Supplemental disclosure of non-cash financing activity:		
Minority interest in Oxis equity transactions	$	22,000

See notes to the condensed consolidated financial statements

TorreyPines Therapeutics, Inc. (formerly Axonyx Inc.)

Notes to Condensed Consolidated Financial Statements
(unaudited)

(1) Financial Statement Presentation

The financial statements presented in this Form 10-Q are for the periods through September 30, 2006. All common stock issued and outstanding, per share amounts and option numbers and disclosures reflect the 1-for-8 reverse stock split completed in connection with the business combination between Axonyx Inc., or Axonyx, and TorreyPines Therapeutics, Inc., as described in Note (8) below. The financial statements presented in this Quarterly Report on Form 10-Q reflect the historical financial statements of Axonyx Inc., which changed its name to TorreyPines Therapeutics, Inc. in connection with the business combination, but do not otherwise reflect the effect of the closing of the business combination which occurred on October 3, 2006.

The unaudited condensed consolidated financial statements 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 necessary to present fairly the financial position at September 30, 2006, and the results of operations and cash flows for the quarterly and nine month periods presented. Certain information and footnote disclosure normally included in 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, 2005, included in the our Annual Report on Form 10-K, and Amendment No. 1 to the Form S-4 filed on August 25, 2006. The results for the interim periods are not necessarily indicative of the results for the full fiscal year. Certain prior year amounts have been reclassified to conform to current year presentation.

Principles of consolidation

The consolidated financial statements include the accounts of Axonyx Europe, B.V., a wholly owned subsidiary organized in The Netherlands. The financial statements also include the accounts of OXIS International Inc. (OXIS) from the acquisition date of January 15, 2004, when we acquired approximately 52% of the common voting stock of OXIS, through February 28, 2005. Our ownership in OXIS was reduced to 34% on December 31, 2004 as the result of a third party financing by OXIS, however, the accounts of OXIS continued to be consolidated as we controlled the board of directors through a majority of the OXIS board seats. On February 28, 2005 OXIS announced that Mr. Steven T. Guillen had joined OXIS as President and Chief Executive Officer and as a member of the OXIS Board of Directors. Consequently we no longer had a majority of the seats on the OXIS Board, and, beginning March 1, 2005, OXIS is no longer consolidated but rather accounted for using the equity method.

(2) Investment in OXIS International, Inc.

As described above, since March 1, 2005, we account for our investment in OXIS under the equity method of accounting, as prescribed by Accounting Principles Board Opinion No. 18 The Equity Method of Accounting for Investments in Common Stock .

We own approximately 14 million common shares of OXIS International Inc., approximately 32% of the OXIS outstanding capital stock, with a carrying value at September 30, 2006 of $4,089,000. OXIS is traded on the bulletin board (OXIS.OB) with relatively little trading volume. At September 30, 2006, the quoted market value of these shares was $0.21 per share ($2,940,000).

(3) Investments

We invest in auction-rate securities (ARS) that are held as investments available for sale. Auction rate securities are instruments with long-term underlying maturities, but for which an auction is conducted periodically, as specified, to reset the interest rate and allow investors to buy or sell the instruments. Because auctions generally occur more often than annually, and because we hold these instruments in order to meet short-term liquidity needs, the auction rate securities are classified as short-term investments in the Condensed Consolidated Balance Sheet. Consistent with our other securities that are classified as available-for-sale, the Condensed Consolidated Statement

of Cash Flows reflects the gross amount of the purchases of auction rate securities and the proceeds from sales of auction rate securities.

(4) Stock-based Compensation

In 2000, our Board of Directors and stockholders approved a Stock Option Plan (2000 Plan) which, as amended, provides for the granting of options to purchase up to 250,000 shares of common stock and pursuant to which officers, directors, advisors and consultants are eligible to receive incentive and/or non-statutory stock options. Incentive stock options granted under the 2000 Plan are exercisable for a period of up to 10 years from date of grant at an exercise price which is not less than the fair value on date of grant, except that the exercise period of options granted to a stockholder owning more than 10% of the outstanding stock may not exceed five years and their exercise price may not be less than 110% of the fair value of the common stock at date of grant. Vesting of 2000 Plan options varies from fully vested at the date of grant to multiple year apportionment of vesting as determined by the Board of Directors. Pursuant to the 2000 Plan as amended, 93,750 options were added to the share reserve effective January 1, 2003 and January 1, 2004. On March 30, 2004, we amended the 2000 Plan to increase the aggregate number of shares from 437,500 to 937,500. Stockholder approval for the increase was received in June 2004.

Commencing January 1, 2006 we adopted Statement of Financial Accounting Standard No. 123R, Share Based Payment (SFAS 123R) , which requires all share-based payments, including grants of stock options, to be recognized in the statement of operations as an operating expense, based on fair values.

Prior to adopting SFAS 123R, we accounted for stock-based employee compensation under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees . We have applied the modified prospective method in adopting SFAS 123R. Accordingly, periods prior to adoption have not been restated.

As discussed in Note 9, we approved a 1-for-8 reverse stock split effective October 3, 2006. All common stock issued and outstanding per share amounts and option numbers and disclosures reflect the reverse split.

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 for the three and nine months ended September 30, 2005 when APB opinion No. 25 was followed.

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Reported net loss attributable to common stockholders	$ (5,687,000)	$ (24,299,000)
Stock-based employee compensation included in net loss	32,000	116,000
Stock-based employee compensation determined under the fair value based method	(511,000)	(1,821,000)
Pro forma net loss	$ (6,166,000)	$ (26,004,000)
Loss per common share attributable to common stockholders (basic and diluted):		
As reported	$ (0.85)	$ (3.62)
Pro forma	$ (0.92)	$ (3.88)

As of September 30, 2006, there was $1,365,000 of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under existing stock option plans. This cost is expected

to be recognized over a weighted-average period of 1.3 years. The total fair value of shares vested during the nine months ended September 30, 2006 was $1,292,000.

We use the Black-Scholes option pricing model to determine the weighted average fair value of options. The fair value of options at date of grant and the assumptions utilized to determine fair value are indicated in the following table:

	Nine Months Ended September 30,	
	2006	**2005**
Weighted average fair value at date of grant for options granted during the period	$ 6.40	$ 8.24
Risk-free interest rates	4.57 4.82%	3.77% - 4.33%
Expected option life in years	10	10
Expected stock price volatility	.90 93	.94 - .97
Expected dividend yield	-0-	-0-

Under SFAS 123R forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate. Under SFAS 123 and APB 25, we elected to account for forfeitures when awards were actually forfeited, at which time all previous pro-forma expense was reversed to reduce pro- forma expense for the period. As of September 30, 2006, all outstanding options were expected to vest per severance and change of control agreements.

The following summarizes our stock option activity for the nine months ended September 30, 2006.

	Shares	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term (Years)**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2005	665,000	$ 31.76		
Granted	53,000	7.28		
Exercised				
Canceled or expired	(30,000)	33.44		
Outstanding at September 30, 2006	688,000	$ 29.84	5.80	$ 66,000
Exercisable at September 30, 2006	556,000	$ 32.40	5.05	$ 55,000

The following summarizes the activity of our non-vested stock options for the nine months ended September 30, 2006.

	Shares	**Weighted Average Fair Value**
Nonvested at December 31, 2005	129,000	$ 23.04
Granted	53,000	$ 7.28
Vested	(50,000)	$ 16.88
Nonvested at September 30, 2006	132,000	$ 19.04

(5) Operating Segments

Beginning March 1, 2005, the OXIS segment reflects our share of OXIS losses under the equity method. Prior to that date, we were organized into two reportable segments: Axonyx and OXIS.

The following table presents information about our two operating segments for the quarter and nine months ended September 30, 2005:

	Axonyx Inc.	OXIS Int l Inc.	Total
Quarter ended September 30, 2005			
Segment Loss	$ (5,579,000)	$ (108,000)	$ (5,687,000)
Nine months ended September 30, 2005			
Revenue including minority interest		$ 403,000	$ 403,000
Segment loss	$ (23,865,000)	$ (434,000)	$ (24,299,000)

(6) Stockholder Rights Plan

We adopted a stockholder rights plan on May 16, 2005. The stockholder rights plan is designed to protect stockholders in realizing fair value and equal treatment in the event of an attempted takeover of the company and to protect us and our stockholders against coercive takeover tactics. The plan was not adopted as a result of any existing or proposed potential takeover threat.

Under the terms of the plan, we distributed one purchase right for each share of common stock outstanding to stockholders at the close of business on May 27, 2005. We will not issue a separate certificate for the rights unless and until they become exercisable.

Each right entitles the holder to purchase from us one one-thousandth of a share of a new series of participating preferred stock at an initial purchase price of $15. The rights will become exercisable and will detach from the common stock for a specified period after any person or group, without the approval of our board of directors, has become the beneficial owner of, or commences a tender offer or exchange offer for, 15% or more of the then outstanding shares of our common stock (subject to certain exceptions).

(7) Reclassification

During the quarter ended September 30, 2005 we reclassified the majority of what had previously been classified as cash and cash equivalents to investments. We follow FASB 115 in determining the appropriate classification for cash equivalents and investments. We have invested in ARS that are held as investments available-for-sale. After the initial issuance of these securities, the interest rate is reset periodically. We have invested in ARS that reset as to interest rate every 28 days.

We have determined that auction rate securities should be classified as investments because the stated or contractual maturities are generally 20 to 30 years. From an economic viewpoint, these securities are priced and traded as short-term investments because of the interest rate reset feature. Accordingly, we have reclassified all such ARS as investments for all periods presented.

(8) Business Combination with TorreyPines Therapeutics, Inc.

On October 3, 2006, we completed the business combination between Axonyx Inc. and TorreyPines Therapeutics, Inc., a private company, or TPTX, in accordance with the terms of the Agreements and Plan of Merger and Reorganization among Axonyx, TPTX and Autobahn Acquisition, Inc., dated as of June 7, 2006 and amended as of August 23, 2006. Pursuant to the terms of the merger agreement, TPTX merged with and into Autobahn Acquisition, Inc., became our wholly owned subsidiary and changed its name to TPTX, Inc. In connection with the business combination we effected a 1-for-8 reverse stock split of our common stock and changed our state of incorporation from Nevada to Delaware. We also changed our name to TorreyPines Therapeutics, Inc. and changed our ticker symbol on the Nasdaq Global Market to TPTX.

Under the terms of the merger agreement, we issued shares of our common stock to the TPTX stockholders. Holders of TPTX preferred stock also received a warrant to purchase shares of our common stock. We assumed all of the stock options and warrants of TPTX outstanding as of October 3, 2006, such that the former TPTX stockholders, option holders and warrant holders owned, as of the closing of the business combination, approximately 58% of our common stock on a fully-diluted basis and the stockholders, options holders and warrant holders of Axonyx prior to the business combination owned, as of the closing, approximately 42% of our common stock on a fully-diluted basis. Following completion of the business combination and the reverse stock split, we now have approximately 15.7 million shares of our common stock outstanding.

The issuance of the shares of common stock to the former stockholders of TPTX was registered with the Securities and Exchange Commission on a Registration Statement on Form S-4 (Reg. No. 333-136018) which was originally filed on July 25, 2006 and amended on August 25, 2006.

With the completion of the business combination, we will update and reassess our business plan and drug candidate portfolio prioritization.

(9) Pro Forma Financial Information

We filed a Current Report on Form 8-K on October 10, 2006 and will file an amendment to that Current Report on Form 8-K on or before December 13, 2006 that will include the required pro forma financial information. Unaudited pro forma condensed combined financial statements for the six months ended June 30, 2006 and twelve months ended December 31, 2005 were included in the Amendment No. 1 to the S-4 Registration Statement, filed on August 25, 2006.

(10) Legal Proceedings

Several lawsuits were filed against us in February, 2005, in the U.S. District Court of the Southern District of New York asserting claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of our common stock during the period from June 26, 2003, through and including February 4, 2005 referred to as the Class Period. Dr. Marvin S. Hausman (a current director and former Chief Executive Officer), and Dr. Gosse B. Bruinsma (former Chief Executive Officer) were also named as defendants in the lawsuits. These actions were consolidated into a single class action lawsuit in January 2006. On April 10, 2006 the plaintiff filed an amended consolidated complaint. We filed our answer to that complaint on May 26, 2006. Our motion to dismiss the consolidated amended complaint was filed on May 26, 2006 and will be submitted to the court for a decision following the parties filing of their legal briefs. The class action plaintiffs allege, generally, that our Phase III Phenserine development program was subject to alleged errors of design and execution which resulted in the failure of the first Phase III Phenserine trial to show efficacy. Plaintiffs allege the defendants failure to disclose the alleged defects resulted in the artificial inflation of the price of our shares during the Class Period.

There is also a stockholder derivative suit pending in New York Supreme Court (New York County) against current and former directors and officers of the former Axonyx. The named defendants are Marvin S. Hausman, Gosse B. Bruinsma, S. Colin Neill, Louis G. Cornacchia, Steven H. Ferris, Gerald J. Vlak, Ralph Snyderman and Michael A. Griffith. Defendants are alleged to have breached their duties to us and misused inside information regarding clinical trials of Phenserine. This action has been stayed pending further developments in the federal class action.

The complaints seek unspecified damages. We believe the complaints are without merit and intend to defend these lawsuits vigorously. However, we cannot make assurances that we will prevail in these actions, and, if the outcome is unfavorable to us, our reputation, operations and share price could be adversely affected.

(11) New Accounting Pronouncement

In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109 (FIN 48), which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We do not expect the adoption of FIN 48 to have a material impact on our financial reporting, and we are currently evaluating the impact, if any, the adoption of FIN 48 will have on our disclosure requirements.

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, as defined in the Private Securities Litigation Reform Act of 1995 that are based on current expectations, estimates and projections. Statements that are not historical facts, including statements about our beliefs and expectations, are forward-looking statements. These statements involve potential risks and uncertainties; therefore, actual results may differ materially. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they were made. We do not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Because the business combination of TPTX and Axonyx was not completed until October 3, 2006, the discussion of historical financial condition and results of operations addresses the interim financial statements of Axonyx and does not address the financial condition or results of operations of TPTX. For additional financial information on TPTX please see the selected historical consolidated financial data of TPTX, the selected unaudited pro forma condensed financial date of the combined company, and other materials filed with, or incorporated by reference into, Amendment No. 1 to our Form S-4 filed on August 25, 2006 with the Securities and Exchange Commission, or SEC.

We refer you to the Axonyx Inc. Annual Report on Form 10-K for the year ended December 31, 2005 filed with the SEC, where the risks set forth below and others are more fully described, as well as Amendment No. 1 to the Form S-4 filed on August 25, 2006.

Specifically, with respect to our drug candidates, we cannot assure our stockholders that: any preclinical studies or clinical trials will prove successful, and if successful, that the results could be replicated; safety and efficacy profiles of any of our drug candidates will be established, or if established, will remain the same, be better or worse in future clinical trials, if any; any of our drug candidates will support a New Drug Application, or NDA, filing, will be approved by the United States Food and Drug Administration, or FDA, or if approved, will prove competitive in the market; we will be able to successfully out-license any of our drug candidates; we will be able to successfully in-license any additional compounds, or that we will obtain the necessary financing to support our drug development program.

We do not undertake to discuss matters relating to our ongoing clinical trials or our regulatory strategies beyond those which have already been made public or discussed herein.

Overview

The description that follows refers to our compounds as of September 30, 2006, prior to the combination with TPTX.

We are a biopharmaceutical company, specializing in central nervous system, or CNS, neurodegenerative diseases, engaged in the business of acquiring patent rights to clinical stage compounds, compounds with strong proof of concept data and compounds ready for proof of concept validation with convincing scientific rationale, or potentially another company with similar rights. We further develop and add value to these compounds and then seek to out-license or partner them when we believe it business prudent. We have acquired patent rights to three main classes of therapeutic compounds designed for the treatment of Alzheimer s disease, or 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 in cows, and Scrapies disease in sheep. We have licensed these patent rights from New York University. We also have co-ownership rights to patent applications regarding the therapeutic compound named Posiphen designed for the treatment of AD progression and Bisnorcymserine, or BNC, in development for the treatment of severe AD.

Our mission is to be a leading biopharmaceutical company that develops products and technologies to treat central nervous system disorders. Our initial business strategy has been focused primarily on three compounds in development for AD. These are:

Phenserine A symptomatic and disease progression treatment of mild to moderate AD

Posiphen A disease progression treatment for AD

Bisnorcymserine (BNC) A symptomatic and disease progression treatment for AD

Phenserine is an inhibitor of acetylcholinesterase for the potential treatment of mild to moderate AD. Acetylcholinesterase is an enzyme active in the nerve synapse that degrades the neurotransmitter acetylcholine in the brain and other tissues of the body. Acetylcholinesterase inhibitors are drugs designed to selectively inhibit acetylcholinesterase. Acetylcholine is a neurotransmitter or a chemical substance that sends signals between neurons or nerve cells. Neurotransmitters are secreted by neurons into the space between neurons called the synapse. Acetylcholine is a primary neurotransmitter in the brain, and is associated with memory and cognition. Inhibition of its breakdown in AD patients has been shown to improve memory and cognition.

Posiphen is a compound that, in animal models, appears to decrease the formation of the beta amyloid precursor protein, or beta-APP, and amyloid with potential applications in the treatment of AD progression. Posiphen is the positive isomer of Phenserine. As such, it appears to affect the messenger RNA of beta-APP as well as inhibit beta secretase whereby levels of neurotoxic beta amyloid, in preclinical animal models, are reduced.

Bisnorcymserine is a butyrylcholinesterase inhibitor. Butyrylcholinesterase is found in high concentration in the plaques taken from individuals who have died from AD. Butyrylcholinesterase is an enzyme that is normally found widely in the body and butyrylcholine appears to play a role in the progression of AD. Inhibition of the enzyme may prove valuable in the treatment of severe AD.

The completion of the business combination on October 3, 2006 will allow us to update and reassess our business plan, drug candidate portfolio prioritization and liquidity needs.

RESULTS OF OPERATIONS

Revenues

We had no revenue for the quarters ended September 30, 2006 and 2005. We had no revenue for the nine months ended September 30, 2006 and $403,000 in revenue for the nine months ended September 30, 2005. Revenue in 2005 was derived exclusively from the sale of research assays and fine chemicals at OXIS. The reduction in revenue in 2006 from prior year levels results from the fact that OXIS operations are no longer being consolidated with our results effective March 1, 2005 as discussed in Note 1 and 2 to the condensed consolidated financial statements.

Costs of Sales

Our costs of sales were entirely related to our subsidiary, OXIS. The percentage of cost of sales for the nine months ended September 30, 2005 was 52%.

Research and Development

Research and development expenses were $1,354,000 and $5,135,000 for the quarters ended September 30, 2006 and 2005, respectively. Research and development costs declined by $3,781,000 from the prior year s quarter ended September 30, 2005. This reduction reflects a decline in Phenserine program expenditures of $2,794,000 due to the completion/curtailment of the Phenserine trials in late 2005. In addition Posiphen and BNC program expenditures for chemical, manufacturing costs and preclinical costs declined by $1,307,000. These reductions are offset in part by $277,000 in non cash employee option charges incurred related to the adoption of SFAS 123(R) as discussed in Note 4 in the notes to consolidated financial statements. Additional research and development expense reductions include research project costs, insurance and salary expenses.

Research and development expenses were $6,973,000 and $21,808,000 for the nine months ended September 30, 2006 and 2005, respectively. Research and development costs declined by $14,835,000 from the nine months ended September 30, 2005. This reduction reflects a decline in Phenserine program expenditures of $15,097,000 due to the completion/curtailment of the Phenserine trials in late 2005 and a reduction in Posiphen program expenditures of $549,000. This reduction is offset, in part, by increased expenditures of $345,000 in the BNC program and $804,000 in non cash employee option charges incurred related to the adoption of SFAS 123(R).

General and Administrative

12

General and administrative expenses were $884,000 and $1,018,000 for the quarters ended September 30, 2006 and 2005, respectively. General and administrative expenses decreased $134,000 compared to the prior year s quarter ended September 30, 2005. This decrease is attributed to a $379,000 decrease in professional fees and a decrease of $43,000 in state and local franchise taxes. These decreases are offset in part by a $183,000 increase in non-cash charges related to employee stock option grants related to the adoption of SFAS 123(R) as discussed in Note 4 in the notes to consolidated financial statements and an increase in salary costs of $127,000 primarily attributed to bonuses.

General and administrative expenses were $4,437,000 and $3,894,000 for the nine months ended September 30, 2006 and 2005, respectively. General and administrative expenses increased $543,000 from the nine months ended September 30, 2005. This increase is attributed to a $400,000 increase in patent acquisition costs and a $608,000 increase in non-cash charges related to stock option grants to consultants and employees. These increases are offset in part by a $130,000 reduction in investor relations costs, a $332,000 reduction in OXIS expenses which are no longer consolidated with our results effective March 1, 2005 as discussed in Notes 1 and 2 to the condensed consolidated financial statements and various other reductions in general and administrative expenses.

Merger Costs

Costs incurred as a result of the business combination of Axonyx Inc. and TorreyPines Therapeutics, Inc., as discussed in Note 9, are comprised of $2,746,000 in severance payments, $1,624,000 in financial advisor fees, $746,000 in legal fees, $127,000 in proxy solicitation costs and $103,000 in miscellaneous termination costs.

Other Income (Expense)

Investment income was $631,000 and $586,000 for the quarters ending September 30, 2006 and 2005, respectively. Investment income was $1,963,000 and $1,716,000 for the nine months ended September 30, 2006 and 2005, respectively. Investment income reflects the decline in cash and investment balances offset by a rise in short term interest rates.

Foreign exchange losses for the quarters ended September 30, 2006 and 2005 were $11,000 and $14,000, respectively. Foreign exchange losses of $34,000 and $95,000 were incurred for the nine months ended September 30, 2006 and 2005, respectively. The decline in foreign exchange losses reflects more stable exchange rates and a decline in the volume of Euro denominated transactions which reflects the completion of Phenserine trials occurring in Europe in late 2005.

Gain on issuance of subsidiary stock was $84,000 and $162,000 net for the three and nine months ended September 30, 2006, respectively. This gain on issuance of subsidiary stock results from common stock equity transactions in OXIS.

Equity in loss of OXIS of $210,000 and $625,000 reflects our proportional share of OXIS losses for the three and nine months ended September 30, 2006 respectively, under the equity method of accounting.

Net Loss

We experienced net losses of $7,090,000 ($1.06 per share-basic and diluted) and $5,687,000 ($0.85 per share-basic and diluted) for the quarters ended September 30, 2006 and 2005, respectively. We experienced net losses of $15,290,000 ($2.28 per share basic and diluted) and $24,299,000 ($3.62 basic and diluted) for the nine months ended September 30, 2006 and 2005, respectively. The decrease in the loss for the nine month period is primarily attributed to business combination costs incurred in 2006 related to the business combination of Axonyx Inc. and TorreyPines Therapeutics, Inc., as discussed in Note 9. These costs are offset in part by a decline in Phenserine program expenditures due to the completion/curtailment of the Phenserine program in late 2005. The increase in the loss for the quarter is attributed to the business combination costs incurred offset in part by a decline in research and development costs.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2006 we had $46,652,000 in cash, cash equivalents and investments, and $40,246,000 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 stockholder.

Net cash used in operating activities for the nine months ended September 30, 2006 was $11,686,000 resulting principally from a net loss of $15,290,000 and a decline of $1,668,000 in accounts payable. These declines are offset in part by non-cash expenses of $376,000 in depreciation and amortization, $1,303,000 in compensation related to options and warrants issued for services, $625,000 in equity in loss of OXIS and $2,636,000 increase in accrued expenses.

Net cash provided by investing activities for the nine month ended September 30, 2006 resulted from investment sales and maturities in excess of investment purchases.

We believe that we have sufficient capital resources to finance our plan of operation at least through December 31, 2007. However, as this is a forward-looking statement, and there may be changes that could consume available resources significantly before such time including the impact of the business combination of Axonyx Inc. and TorreyPines Therapeutics, Inc. (see Note 8 to Financial Statements above), our long term capital requirements may change. The adequacy of our available funds will depend on many factors, including portfolio development priorities, eventual contract costs of undertaking large later stage clinical trials with any of our compounds under development, the potential cost of acquiring or developing compounds that we may license in, regulatory delays, patent costs for filing, prosecuting, maintaining and defending our patent rights, and defending our current class action securities litigation, among others.

We may periodically seek potential equity financing, sub-licensing and other collaborative arrangements that may generate additional capital for us in order to support our research and development activities. We cannot assure you that we will generate sufficient additional capital or revenues, if any, to fund our operations beyond December 31, 2007, 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 completion of the business combination on October 3, 2006 will allow us to update and reassess our business plan, drug candidate portfolio prioritization and liquidity needs.

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 Annual Report on Form 10-K for the year ended December 31, 2005. Our critical accounting policies are:

Principles of consolidation: The consolidated financial statements include the accounts of Axonyx Europe, B.V., a wholly owned subsidiary organized in The Netherlands. The financial statements also include the accounts of OXIS from the acquisition date of January 15, 2004 when we acquired approximately 52% of the common voting stock of OXIS. Our ownership in OXIS was reduced to 34% on December 31, 2004 as the result of a third party financing by OXIS. Although we had less than a majority ownership at December 31, 2004, the accounts of OXIS continued to be consolidated as we then controlled the board of directors of OXIS. Effective March 1, 2005 we no longer controls the OXIS board. Thus the financial statements of OXIS have been consolidated through February 28, 2005 and equity method accounting has been applied beginning March 1, 2005. All intercompany balances and transactions have been eliminated in consolidation.

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. Right 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.

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

Stock-based compensation: Commencing January 1, 2006 we adopted Statement of Financial Accounting Standard No. 123R, Share Based Payment (SFAS 123R), which requires all share-based payments, including grants of stock options, to be recognized in the statement of operations as an operating expense, based on fair values on grant date. Prior to adopting SFS 123R, we accounted for stock-based employee compensation under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees. We have applied the modified prospective method in adopting SFAS 123R. Accordingly, periods prior to adoption have not been restated.

Accounting for Investment in OXIS: Beginning March 1, 2005, we account for our investment in OXIS under the equity method of accounting, as prescribed by Accounting Principles Board Opinion No. 18 The Equity Method of Accounting for Investments in Common Stock . Pursuant to APB No. 18 a loss in value of an investment which is other than a temporary decline should be recognized the same as a loss in value of other long-term assets.

Accounting for stock sales by OXIS: We account for stock sales by a OXIS in accordance with SEC Staff Accounting Bulletin No. 51. Sales of shares by OXIS result in a change in the carrying value of the investment in OXIS.

Subsequent Event

With the completion of the business combination of TPTX and Axonyx on October 3, 2006, we will update and reassess our business plan and drug candidate portfolio prioritization. In addition to the compounds described in the Overview section above, the following describes our additional development programs as a result of the business combination.

We discover and develop novel small molecules to treat diseases and disorders of the central nervous system, or CNS, including migraine, chronic pain, and cognitive disorders including Alzheimer s disease, or AD and cognitive impairment associated with schizophrenia. Our migraine and chronic pain franchise is comprised of two product candidates that were in-licensed from Eli Lilly and Company in 2003. Both product candidates are in clinical development. The lead product candidate, tezampanel, has been studied in two Phase I and five Phase IIa clinical trials. The five Phase IIa trials were double-blind, placebo-controlled trials that evaluated the safety and efficacy of tezampanel, given intravenously, in validated proof of concept models for migraine, post-operative pain, and neuropathic pain. In all studies, tezampanel was shown to be more effective than placebo. We initiated a Phase IIb study of tezampanel given subcutaneously to patients with migraine in October 2006. Our second compound for pain is NGX426, an orally administered form of tezampanel. NGX426 has been evaluated in preclinical studies, and in October 2006, we reported results of a Phase I clinical study with NGX426. This Phase I study was a double blind, placebo-controlled, ascending-dose, sequential cohort study designed to evaluate the safety, tolerability and pharmacokinetics of NGX426, as well as to determine the rate and extent of conversion of the prodrug, NGX426, to the active drug tezampanel. The drug was shown to be safe and well tolerated at all doses tested and pharmacokinetic analyses suggest rapid conversion of NGX426 to tezampanel. Initially, we intend to develop NGX426 as a treatment for migraine with additional development targeted toward chronic pain conditions such as neuropathic pain.

Our franchise for cognitive disorders includes three product candidates. One product candidate is in clinical development and the other two are in preclinical testing. We believe that these product candidates will either improve cognition associated with Alzheimer s disease or schizophrenia or may delay the onset or slow the progression of AD by targeting the underlying disease mechanism. The most advanced compound, NGX267, in development for cognitive disorders is an orally administered muscarinic agonist that was in-licensed from Life Science Research Israel, or LSRI, in 2004. We have completed one Phase I single dose study of NGX267 in healthy adult males. A second study, of similar design, was conducted in healthy elderly male and females. We currently expect to initiate a Phase I multiple dose study of NGX267 by mid-2007. Our two additional product candidates in our cognitive disorders franchise are in preclinical testing. NGX292, a follow-on muscarinic agonist, is a metabolite of NGX267, was also in-licensed from LSRI and has a similar mechanism of action to NGX267. NGX555 was discovered by our scientists. NGX555 is the lead compound in a series of potent compounds, and it is targeted to be developed to delay the onset or to slow the progression of AD.

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. We had a net foreign exchange loss of $34,000 for the nine months ended

September 30, 2006 and a loss of $95,000 for the nine months ended September 30, 2005. If the foreign currency rates were to fluctuate by 10% from rates at September 30, 2006 and 2005, 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. Our policy is 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 and activities, 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-15(e) and 15d-15(e) 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 principal executive officer and principal 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 controls 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 1. Legal Proceedings

Several lawsuits were filed against us in February, 2005, in the U.S. District Court of the Southern District of New York asserting claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of our common stock during the period from June 26, 2003, through and including February 4, 2005, referred to as the Class Period. Dr. Marvin S. Hausman (a current director and former Chief Executive Officer), and Dr. Gosse B. Bruinsma (former Chief Executive Officer) were also named as defendants in the lawsuits. These actions were consolidated into a single class action lawsuit in January 2006. On April 10, 2006 the Plaintiff filed an amended consolidated complaint. We filed our answer to that complaint on May 26, 2006. Our motion to dismiss the consolidated amended complaint was filed on May 26, 2006 and will be submitted to the court for a decision following the parties filing of their legal briefs. The class action plaintiffs allege, generally, that our Phase III Phenserine development program was subject to alleged errors of design and execution which resulted in the failure of the first Phase III Phenserine trial to show efficacy. Plaintiffs allege the defendants failure to disclose the alleged defects resulted in the artificial inflation of the price of our shares during the Class Period.

There is also a stockholder derivative suit pending in New York Supreme Court (New York County) against current and former directors and officers of the former Axonyx. The named defendants are Marvin S. Hausman, Gosse B. Bruinsma, S. Colin Neill, Louis G. Cornacchia, Steven H. Ferris, Gerald J. Vlak, Ralph Snyderman and Michael A. Griffith. Defendants are alleged to have breached their duties to us and misused inside information regarding clinical trials of Phenserine. This action has been stayed pending further developments in the federal class action.

The complaints seek unspecified damages. We believe the complaints are without merit and intend to defend these lawsuits vigorously. However, we cannot make assurances that we will prevail in these actions, and, if the outcome is unfavorable to us, our reputation, operations and share price could be adversely affected.

Item 1A. Risk Factors.

You should carefully consider the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q and in our other public filings in evaluating our business. If any of the following risks actually occur, our business, operating results and financial condition could be adversely affected. This could cause the price of our stock to decline. This Quarterly Report on Form 10-Q contains, in addition to historical information, forward-looking statements, including statements about future plans, objectives, and intentions that involve risks and uncertainties. Our actual results may differ materially from the results discussed in the forward-looking statements. Factors that might cause or contribute to these differences include those discussed below and elsewhere in this quarterly report. References to we , us and our in these risk factors refer to our operations following the merger of TPTX and Axonyx.

The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing changes, including any material changes, from the risk factors previously disclosed in our report on Form 10-K for the year ended December 31, 2005, as filed with the Securities and Exchange Commission.

Our stock price has been, and is expected to be, volatile, and the market price of our common stock may drop following the merger.

The market price of our common stock could be subject to significant fluctuations following the merger. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of the company s post-merger common stock to fluctuate include:

- the results of our current and any future clinical trials of our product candidates;
- the results of ongoing preclinical studies and planned clinical trials of our preclinical product candidates;
- the entry into, or termination of, key agreements, including key strategic alliance agreements;
- the results and timing of regulatory reviews relating to the approval of our product candidates;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;
- failure of any of our product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the results of clinical trials conducted by others on drugs that would compete with our product candidates;
- issues in manufacturing our product candidates or any approved products;
- the loss of key employees;
- the introduction of technological innovations or new commercial products by our competitors;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- future sales of our common stock;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

Our management will be required to devote substantial time to comply with public company regulations.

As a public company, we will incur significant legal, accounting and other expenses that TPTX did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the NASDAQ Global Market, impose various requirements on public companies, including with respect to corporate governance practices. Our management and other personnel will

need to devote a substantial amount of time to these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs relative to those of TPTX prior to the merger and will make some activities more time-consuming and costly.

In addition, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of its internal controls over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require that we incur substantial accounting and related expense and expend significant management efforts. We will need to hire additional accounting and financial staff to satisfy the ongoing requirements of Section 404. Moreover, if we are not able to comply with the requirements of Section 404, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the NASDAQ Global Market, SEC or other regulatory authorities.

Anti-takeover provisions in our stockholder rights plan and in our certificate of incorporation and bylaws may prevent or frustrate attempts by stockholders to change the board of directors or current management and could make a third-party acquisition difficult.

We are a party to a stockholder rights plan, also referred to as a poison pill, which is intended to deter a hostile takeover of us by making such proposed acquisition more expensive and less desirable to the potential acquirer. The stockholder rights plan and our certificate of incorporation and bylaws, as amended, contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

We may continue to incur losses for the foreseeable future, and might never achieve profitability.

We have incurred net operating losses every year since each of their respective inceptions. We may never become profitable, even if we are able to commercialize our products. We will need to conduct significant research, development, testing and regulatory compliance activities that, together with projected general and administrative expenses, is expected to result in substantial increased operating losses for at least the next several years. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

If we lose key personnel or are unable to attract and retain additional personnel, we may be unable to pursue collaborations or develop our own products.

The loss of any key members of our scientific or management staff, or failure to attract or retain other key scientific employees, could prevent us from pursuing collaborations or developing our products and core technologies. Recruiting and retaining qualified scientific personnel to perform research and development work are critical to our success. There is intense competition for qualified scientists and managerial personnel from numerous pharmaceutical and biotechnology companies, as well as from academic and government organizations, research institutions and other entities. In addition, we will rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. All of our consultants and advisors will be employed by other employers or be self-employed, and will have commitments to or consulting or advisory contracts with other entities that may limit their availability to us.

We may be required to suspend, repeat or terminate our clinical trials if we do not meet regulatory requirements, the results are negative or inconclusive, or if the trials are not well designed.

Before regulatory approval for any potential product can be obtained, we must undertake extensive clinical testing in humans to demonstrate the tolerability and efficacy of the product, both on its own terms, and as compared to the other principal drugs on the market that have the same therapeutic indication. We cannot assure investors that we will obtain authorization to permit product candidates that are already in the preclinical development phase to enter the human clinical testing phase. In addition, we cannot assure investors that we will successfully complete any authorized preclinical or clinical testing within any specified time period, or without significant additional resources or expertise to those originally expected to be necessary. We cannot assure investors that such testing will show potential products to be safe and efficacious or that any such product will be approved for a specific indication. Further, the results from preclinical studies and early clinical trials may not be indicative of the results that will be obtained in later-stage clinical trials. In addition, we, or regulatory authorities, may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks.

Completion of clinical tests depends on, among other things, the number of patients available for testing, which is a function of many factors, including the number of patients with the relevant conditions, the nature of the clinical testing, the proximity of patients to clinical testing centers, the eligibility criteria for tests as well as

competition with other clinical testing programs involving the same patient profile but different treatments. We will rely on third parties, such as contract research organizations and/or co-operative groups, to assist it in overseeing and monitoring clinical trials as well as to process the clinical results and manage test requests, which may result in delays or failure to complete trials, if the third parties fail to perform or to meet the applicable standards. A failure by us or such third parties to keep to the terms of a product program development for any particular product candidate or to complete the clinical trials for a product candidate in the envisaged time frame could have significant negative repercussions on our business and financial condition.

If clinical trials of our product candidates do not produce successful results, we will be unable to commercialize resulting products and our business will be materially adversely affected.

To receive regulatory approval for the commercialization of any of our product candidates, we must conduct clinical trials to demonstrate safety and efficacy in humans. We cannot predict whether we will encounter problems with any of our planned clinical trials that will cause us or regulatory authorities to delay or suspend clinical trials, or delay the analysis of data from our ongoing clinical trials. Any of the following factors could delay the clinical development of our product candidates:

ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of one or more clinical trials;

delays in receiving, or the inability to obtain, required approvals from institutional review boards or other; reviewing entities at clinical trial sites selected for participation in a clinical trials;

delays or slower than anticipated enrollment of participants into clinical trials;

lower than anticipated retention rate of participants in clinical trials;

need to repeat clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;

inadequate supply or deficient quality of product candidate materials or other materials necessary to conduct its clinical trials;

unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;

serious, unexpected or undesirable side effects experienced by participants in the clinical trials that delay or preclude regulatory approval or limit the commercial use or market acceptance if approved;

findings that the trial participants are being exposed to unacceptable health risks;

placement by the FDA of a clinical hold on a trial;

restrictions on or post-approval commitments with regard to any regulatory approval we ultimately obtain that renders a product candidate not commercially viable; and

unanticipated cost overruns in preclinical and clinical trials.

Human clinical testing is expensive, can take many years, and has an uncertain outcome. Failure can occur at any stage of human clinical testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future product candidates.

Success in preclinical testing and early clinical trials does not mean that later clinical trials will be successful. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results.

We will need to reach agreement with the FDA on the targeted endpoints for its efficacy clinical trials. In some cases, the FDA may not have validated endpoints established and we may work with the FDA to potentially design and validate one or more endpoints. The FDA may not approve any or all of the endpoints and they may

ultimately decide that the endpoints are inadequate to demonstrate the safety and efficacy levels required for regulatory approval. Our failure to demonstrate the safety and efficacy of its product candidates adequately would jeopardize our ability to achieve regulatory approval for, and ultimately to commercialize the product candidates.

Delays in the commencement or completion of clinical testing of our product candidates could result in increased costs to us and delay our ability to generate significant revenues.

Delays in the commencement or completion of clinical testing could significantly impact our product development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

obtaining regulatory approval to commence a clinical trial;

reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

obtaining sufficient quantities of clinical trial materials for any or all product candidates;

obtaining institutional review board approval to conduct a clinical trial at a prospective site; and

recruiting participants for a clinical trial.

In addition, once a clinical trial has begun, it may be suspended or terminated by us or the FDA or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements;

inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; or

lack of adequate funding to continue the clinical trial.

Clinical trials require sufficient participant enrollment, which is a function of many factors, including the size of the target population, the nature of the trial protocol, the proximity of participants to clinical trial sites, the availability of effective treatments for the relevant disease, the eligibility criteria for our clinical trials and competing trials. Delays in enrollment can result in increased costs and longer development times. Our failure to enroll participants in our clinical trials could delay the completion of the clinical trials beyond current expectations. In addition, the FDA could require us to conduct clinical trials with a larger number of participants than it may project for any of its product candidates. As a result of these factors, we may not be able to enroll a sufficient number of participants in a timely or cost-effective manner.

Furthermore, enrolled participants may drop out of clinical trials, which could impair the validity or statistical significance of the clinical trials. A number of factors can influence the discontinuation rate, including, but not limited to: the inclusion of a placebo arm in a trial; possible lack of effect of the product candidate being tested at one or more of the dose levels being tested; adverse side effects experienced, whether or not related to the product candidate; and the availability of numerous alternative treatment options that may induce participants to discontinue from the trial.

We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time if we or they believe the participants in such clinical trials, or in independent third-party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks or for other reasons.

We cannot predict whether any of our product candidates will encounter problems during clinical trials that will cause us or regulatory authorities to delay or suspend these trials or delay the analysis of data from these trials. In addition, it is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue development of the product candidate that is affected or the development of any of our other product candidates. If we experience significant delays in the

commencement or completion of clinical testing, financial results and the commercial prospects for the product candidates will be harmed, costs will increase and our ability to generate revenues will be delayed.

We may not complete our clinical trials in the time expected, which could delay or prevent the commercialization of our products.

Although for planning purposes we forecast the commencement and completion of clinical trials, the actual timing of these events can vary dramatically due to factors such as delays, scheduling conflicts with participating clinicians and clinical institutions and the rate of patient enrollment. Clinical trials involving our product candidates may not commence nor be completed as forecasted. In certain circumstances we will rely on academic institutions or clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our products. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. These trials may not commence or be completed as we expect. They may not be conducted successfully. Failure to commence or complete, or delays in, any of our planned clinical trials could delay or prevent the commercialization of our products and harm our business.

If we fail to establish and maintain collaborations or if our partners do not perform, we may be unable to develop and commercialize our product candidates.

We have entered into collaborative arrangements with third parties to develop and/or commercialize product candidates. Additional collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize existing and future product candidates. If we fail to maintain our existing collaborative arrangements or fail to enter into additional collaborative arrangements, the number of product candidates from which we could receive future revenues would decline.

Our dependence on collaborative arrangements with third parties will subject it to a number of risks that could harm our ability to develop and commercialize products:

collaborative arrangements might not be on terms favorable to us;

disagreements with partners may result in delays in the development and marketing of products, termination of collaboration agreements or time consuming and expensive legal action;

we cannot control the amount and timing of resources partners devote to product candidates or their prioritization of product candidates, and partners may not allocate sufficient funds or resources to the development, promotion or marketing of our products, or may not perform their obligations as expected;

partners may choose to develop, independently or with other companies, alternative products or treatments, including products or treatments which compete with us;

agreements with partners may expire or be terminated without renewal, or partners may breach collaboration agreements with us;

business combinations or significant changes in a partner s business strategy might adversely affect that partner s willingness or ability to complete its obligations to us; and

the terms and conditions of the relevant agreements may no longer be suitable.

We cannot assure you that we will be able to negotiate future collaboration agreements or that those currently in existence will make it possible for us to fulfill our objectives.

If we fail to keep pace with rapid technological change in the biotechnology and pharmaceutical industries, our products could become obsolete.

Biotechnology and related pharmaceutical technology have undergone and are subject to rapid and significant change. We expect that the technologies associated with biotechnology research and development will

continue to develop rapidly. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. Any compounds, products or processes that we develop may become obsolete before we recover any expenses incurred in connection with developing these products.

We have had clinical trial failures on our lead compound.

We have not achieved statistical significance in the primary endpoints in the Phase III trials conducted to date with our lead compound, Phenserine. We are seeking a partner to continue the development of Phenserine, including conducting additional Phase III trials. These trials are costly. We cannot assure that we will be able to successfully conclude a deal with a partner. If we do find a partner to continue developing Phenserine, we cannot assure that they will successfully develop or commercialize Phenserine.

We are a defendant in a class action lawsuit and a stockholder derivative lawsuit which, if determined adversely, could have a material adverse affect on us.

A class action securities lawsuit and a stockholder derivative lawsuit have been filed against us as described under Item 1 Legal Proceedings. We are defending against these actions vigorously; however, we do not know what the outcome of these proceedings will be and, if we do not prevail, we may be required to pay substantial damages or settlement amounts. Furthermore, regardless of the outcome, we may incur significant defense costs, and the time and attention of our management may be diverted from normal business operations. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could materially and adversely affect our operations and results. In any event, publicity surrounding the lawsuits and/or any outcome unfavorable to us could adversely affect our reputation and share price. The uncertainty associated with substantial unresolved lawsuits could harm our business, financial condition and reputation.

We have certain obligations to indemnify our officers and directors and to advance expenses to such officers and directors. Although we have purchased liability insurance for our directors and officers, if our insurance carriers should deny coverage, or if the indemnification costs exceed the insurance coverage, we may be forced to bear some or all of these indemnification costs directly, which could be substantial and may have an adverse effect on our business, financial condition, results of operations and cash flows. If the cost of our liability insurance increases significantly, or if this insurance becomes unavailable, we may not be able to maintain or increase our levels of insurance coverage for our directors and officers, which could make it difficult to attract or retain qualified directors and officers.

****We have licensed rights to product candidates tezampanel and NGX426 from Eli Lilly & Company, or Eli Lilly. Eli Lilly has rights to negotiate, which could delay or limit our ability to develop and commercialize these product candidates, and rights of termination under the license agreement, which if exercised would adversely affect our business.***

In April 2003, we entered into an agreement with Eli Lilly to obtain an exclusive license from Eli Lilly to their AMPA/kainate, or AK, antagonist assets including our lead product candidate, tezampanel, as well as NGX426. Under the agreement, if we decide to sublicense rights to commercialize either of the product candidates licensed to us under the agreement in the U.S. or all of our rights under the agreement worldwide, we are obligated

first to provide Eli Lilly the opportunity to negotiate with us to obtain those rights. These rights held by Eli Lilly may delay or limit our ability to enter into a sublicense with a third party.

We have obligations to make payments to Eli Lilly under the agreement and to use commercially reasonable efforts to develop and commercialize the product candidates subject to the agreement, including achievement of specified development events within specified timeframes. Eli Lilly may terminate the agreement for uncured material breach of the agreement by us, including any breach of our diligence obligations, if we go into bankruptcy or makes a general assignment of our assets to our creditors, or if we undergo a change of control, unless the party acquiring us in the change of control undertakes all of the obligations under the agreement. If Eli Lilly were to terminate the agreement, we would lose rights to the AK antagonist product candidates, and our business would be adversely affected.

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

Under the terms of our licensing agreements with each of our patent licensors our license to the patent rights covering certain of our drug candidates may be terminated if we fail to meet our obligations to the licensors.

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

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

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

If we receive written notice of our default or material breach of any of our obligations under the licensing agreements, we must cure the default within ninety days under the license with CURE or sixty days (or concerning payments, 30 days) under the license with New York University, or the relevant licensor may terminate the license. After such termination, we would not be entitled to make any further use whatsoever of the licensed patent rights, or any related licensed know-how. Upon termination of our license agreements, we are required to return the licensed technology to our licensors.

We anticipate undertaking similar payment, development milestone, patent prosecution costs, and termination obligations under applications currently pending with NIH for certain patent rights to Posiphen and BNC, if such licenses are granted. Our business and prospects could be adversely affected if either or both of these licenses are not granted.

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

We have licensed rights to product candidates NGX267 and NGX292 from Life Science Research Israel, or LSRI, and LSRI has rights of termination under the license agreement, which if exercised would adversely affect our business.

In May 2004, we entered into an agreement with LSRI to obtain an exclusive license from LSRI to their muscarinic agonist assets NGX267 and NGX292. We have obligations to make payments to LSRI under the agreement and to use commercially reasonable efforts to develop and commercialize the product candidates subject to the agreement, including achievement of specified development events within specified timeframes. LSRI may terminate the agreement for uncured material breach of the agreement by us, including any breach of our diligence obligations, or if we go into bankruptcy, make a general assignment of our assets to our creditors, or dissolve or wind up our business. If LSRI were to terminate the agreement, we would lose rights to the muscarinic agonist product candidates, and our business would be adversely affected.

We depend on Eisai Ltd., or Eisai, for funding for our gamma-secretase modulator program and AD genetics research program. Eisai has the first right to obtain rights to gene targets and compounds resulting from these programs, which could delay or limit our ability to develop and commercialize these gene targets and compounds.

In February 2005, we entered into an agreement with Eisai to discover small molecule gamma-secretase modulator compounds useful in the field of treatment for AD in humans. The agreement has a two-year term and may be extended by Eisai for up to an additional 12 months. In October 2005, we entered into an agreement with Eisai to discover gene targets useful in the field of treatment or prevention of AD in humans. The agreement has a two-year term and may be extended by Eisai for up to an additional 12 months. We depend upon Eisai to provide funding for the research we conduct under these agreements. If Eisai were to cease funding these programs for any reason, we would need to provide our own funding for the programs, seek a strategic partner for further work on the programs, raise additional funding, or curtail or abandon the programs.

During the term of the respective agreements, Eisai has exclusive first rights of negotiation and refusal with regard to a license, collaboration or other arrangement regarding gene targets discovered and validated in the course of the AD genetics research program or compounds discovered and validated in the course of the gamma-secretase modulator program, as applicable. These rights held by Eisai may delay or limit our ability to enter into a license, collaboration or other arrangement for any gene targets resulting from the AD genetic research program or compounds resulting from the gamma-secretase modulator program with a third party.

We have an agreement providing Johnson & Johnson Development Corporation the first right to obtain rights to our M1 agonist program, which could delay or limit our ability to develop and commercialize these product candidates.

We have an agreement with Johnson & Johnson Development Corporation, or JJDC, regarding our research and development work into the effects of using M1 agonists in the treatment of CNS diseases and disorders.

Upon completion of a specified level of development of our lead M1 agonist, we are obligated to provide results for the compound to JJDC.

For a specified period following receipt of the results, or at an earlier time as agreed to by JJDC and us, JJDC has the exclusive right to negotiate with us regarding any sale, transfer, license or other distribution of any our intellectual property rights or products related to our M1 agonist program, referred to as an M1 agonist transaction. If, during the specified period after the end of the period of negotiation with JJDC, we propose to enter in an agreement with a third party regarding an M1 agonist transaction on terms that are equivalent to or less favorable to us than the terms last proposed by JJDC, we must first offer JJDC the right to enter into an agreement with us on the terms proposed by the third party. If JJDC notifies us that it wishes to complete an M1 agonist transaction on the terms offered by the third party within a specified notice period, then the parties will negotiate an agreement on those terms during a specified negotiation period. These rights held by JJDC may delay or limit our ability to enter into an M1 agonist transaction

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

There are significant risks regarding the patent rights surrounding Bisnorcymserine, our potential butyrylcholinesterase inhibitor drug candidate, and Posiphen, a potential pharmaceutical compound for the treatment of AD that is the positive isomer of Phenserine. Because we are not the sole owner of the patent rights, future commercialization of Posiphen or Bisnorcymserine may be adversely impacted by the patent rights held by a third party with whom we do not currently have licensing agreements. We are currently seeking licenses from the third party to reduce or eliminate the risks relating to our development and commercialization efforts. Such licenses may not be available on acceptable terms or at all and may impair our ability to commercialize Bisnorcymserine or Posiphen . A decision not to commercialize these drug candidates could adversely affect our business.

We do not currently have the capability to undertake manufacturing, marketing, or sales of any potential products and we have limited personnel to oversee out-sourced clinical testing and the regulatory approval process.

We have not invested in manufacturing, marketing or product sales resources. We cannot assure you that we will be able to acquire such resources if and when needed. It is likely that we will also need to hire additional personnel skilled in the clinical testing and regulatory compliance process if we develop additional product candidates with commercial potential. We have no history of manufacturing or marketing. We cannot assure you that we will successfully manufacture or market any product we may develop, either independently or under manufacturing or marketing arrangements, if any, with other companies. We currently do not have any arrangements with other companies, and we cannot assure you that any arrangements with other companies can be successfully negotiated or that such arrangements will be on commercially reasonable terms. To the extent that we arrange with other companies to manufacture or market our products, if any, the success of such products may depend on the efforts of those other companies. We do not currently have the capability to conduct clinical testing in-house and do not currently have plans to develop such a capability. We out-source our clinical testing to contract research organizations. We currently have one employee and certain other outside consultants who oversee the contract research organizations involved in clinical testing of our compounds. We cannot assure you that our limited oversight of the contract research organizations will suffice to avoid significant problems with the protocols and conduct of the clinical trials.

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

We have engaged and intend to continue to engage third party contract research organizations, or CROs, and other third parties to help us develop our drug candidates. Although we have designed the clinical trials for our drug candidates, the CROs have conducted all of our clinical trials. As a result, many important aspects of our drug development, pre-clinical and clinical programs have been and will continue to be outside of our direct control. In addition, the CROs may not perform all of their obligations under arrangements with us. If the CROs do not perform clinical trials in a satisfactory manner or breach their obligations to us, the development and commercialization of any drug candidate may be delayed or precluded. We cannot control the amount and timing of resources these CROs

devote to our programs or product candidates. The failure of any of these CROs to comply with any governmental regulations would substantially harm our development and marketing efforts and delay or prevent regulatory approval of our drug candidates. If we are unable to rely on clinical data collected by others, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate its research and development programs or commercialization efforts.

We will need to raise substantial additional capital in the future and additional funding requirements will depend on, and could increase significantly as a result of, many factors, including:

the rate of progress and cost of clinical trials;

the scope of our clinical trials and other research and development activities;

the prioritization and number of clinical development and research programs we pursue;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the costs and timing of regulatory approvals; and

the costs of establishing or contracting for sales and marketing capabilities.

We do not anticipate that we will generate significant continuing revenues for several years, if at all. Until we can generate significant continuing revenues, if ever, we expect to satisfy its future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs or commercialization efforts.

Our success depends upon our ability to protect our intellectual property and proprietary technologies.

Our commercial success depends on obtaining and maintaining patent protection and trade secret protection of our product candidates, proprietary technologies and their uses, as well as successfully defending these patents against third-party challenges. We will only be able to protect its product candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the U.S. The biotechnology patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in its patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

we or our licensors might not have been the first to make the inventions covered by each of its pending patent applications and issued patents;

we or our licensors might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

it is possible that none of our pending patent applications will result in issued patents;

our issued patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties;

our issued patents may not be valid or enforceable;

we may not develop additional proprietary technologies that are patentable; and

the patents of others may have an adverse effect on our business.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect its trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties and proprietary information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect this information. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of any of our collaborators to develop, manufacture, market, and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. We have not conducted a complete search of existing patents to identify existing patents that our product candidates or proprietary technologies may inadvertently infringe.

We may be exposed to future litigation by the companies holding these patents or other third parties based on claims that our product candidates and/or proprietary technologies infringe their intellectual property rights. If one of these patents was found to cover our product candidates, proprietary technologies or their uses, we or our collaborators could be required to pay damages and could be unable to commercialize our product candidates or use our proprietary technologies unless we obtained a license to the patent. A license to these patents may not be available to us or our collaborators on acceptable terms, if at all.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or our collaborators infringe on its technology, we may face a number of issues, including:

infringement and other intellectual property claims which, with or without merit, may be expensive and time-consuming to litigate and may divert management s attention from our core business;

substantial damages for infringement, including treble damages and attorneys fees, as well as damages for products development using allegedly infringing drug discovery tools or methods which we may have to pay if a court decides that the product or proprietary technology at issue infringes on or violates the third party s rights;

a court prohibiting us from selling or licensing the product or using the proprietary technology unless the third party licenses its technology to us, which it is not required to do;

if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross licenses to its technology; and

redesigning our products or processes so they do not infringe, which may not be possible or may require substantial funds and time,

We may also be subject to claims that we or our employees, who were previously employed at universities or other biotechnology or pharmaceutical companies, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential drugs, which could severely harm its business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

Licensing product candidates from other companies, universities or individuals does not always prevent them from developing non-identical but competitive products for their own commercial purposes, nor from pursuing patent protection in areas that are competitive with us. The partners who created these technologies are sophisticated scientists and business people who may continue to do research and development and seek patent protection in the same areas that led to the discovery of the product candidates that they licensed to us. The development and commercialization of successful new drugs from our research program is likely to attract additional research by our licensors in addition to other investigators who have experience in developing products for the memory and cognition market. By virtue of the previous research that led to the discovery of the drugs or product candidates that they licensed to us, these companies, universities, or individuals may be able to develop and market competitive products in less time than might be required to develop a product with which they have no prior experience.

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

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

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

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

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

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

If our drug candidates do not achieve market acceptance, our business may never achieve profitability.

Our success will depend on the market acceptance of any products we may develop. The degree of market acceptance will depend upon a number of factors, including the receipt and scope of regulatory approvals, the establishment and demonstration in the medical community of the safety and effectiveness of our products and their potential advantages over existing treatment methods, generic competition and reimbursement policies of government and third party payors. Physicians, patients, payors or the medical community in general may not accept or utilize any product that we may develop.

The carrying value of our investment in OXIS International may face future impairment.

Effective March 1, 2005, we accounted for our investment in OXIS under the equity method of accounting following accounting principles bulletin (APB) No. 18. Any impairment charge would be required if we determined that any reduction in the OXIS market value over the carry value was permanent.

Item 4. Submission of Matters to a Vote of Security Holders

At Axonyx Inc. s 2006 Annual Meeting of Stockholders held on September 28, 2006, the stockholders:

a) Approved the issuance of Axonyx common stock and the issuance of warrants to purchase Axonyx common stock and the resulting change of control of Axonyx pursuant to the Agreement and Plan of Merger and Reorganization, dated as of June 7, 2006, by and among Axonyx, Autobahn Acquisition, Inc. and TorreyPines Therapeutics, Inc.

For	Against	Abstain
29,300,666	1,140,315	65,971

b) Approved an amendment to Axonyx s articles of incorporation effecting the 1-for-8 reserve stock split.

For	Against	Abstain
28,965,659	1,483,853	57,439

c) Approved an amendment to Axonyx s articles of incorporation to change the name Axonyx Inc. to TorreyPines Therapeutics, Inc.

For	Against	Abstain
48,254,514	1,259,985	99,097

d) Approved a change of Axonyx s state of incorporation from Nevada to Delaware

For	Against	Abstain
29,470,479	968,989	67,484

e) Approved the adoption of the Axonyx Inc. 2006 Equity Incentive Plan

For	Against	Abstain
27,752,093	2,641,952	112,906

f) Voted for the election of six directors

Director	For	Against

Gosse B. Bruinsma, M.D.	48,366,999	1,246,598
Louis G. Cornacchia	47,626,473	1,987,124
Steven H. Ferris, Ph.D.	48,382,489	1,231,108
Marvin S. Hausman, M.D.	48,357,265	1,256,332
Steven B. Ratoff	47,525,352	2,088,245
Ralph Snyderman, M.D.	47,618,169	1,995,428

On October 3, 2006, as described in the Registration Statement on Form S-4, Gosse B. Bruinsma, M.D. and Ralph Snyderman, M.D., resigned from our board of directors effective as of the closing of the merger, and Neil M. Kurtz, M.D., William T. Comer, Ph.D., Peter Davis, Ph.D., Jean Deleage, Ph.D., Jason Fisherman, M.D., and Patrick Van Beneden, each of whom previously served as a director of TPTX, were appointed to our board of

directors effective as of the closing of the merger. These resignations and appointments were made pursuant to the terms of the merger agreement, as amended, which provided TPTX with the authority to designate six individuals as directors. Pursuant to the terms of the merger agreement, as amended, and as described in the Registration Statement on Form S-4, Steven B. Ratoff, Marvin S. Hausman, M.D., Steven Ferris, Ph.D. and Louis Cornacchia will continue to serve on our board of directors.

Item 6. Exhibits.

Number	Exhibits
2.1	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated as of August 23, 2006, between Axonyx Inc. and TorreyPines Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the current report on Form 8-K previously filed on August 23, 2006)
3.1	Certificate of Incorporation of TorreyPines Therapeutics, Inc. dated October 3, 2006. (incorporated by reference to Exhibit 3.1 to the current report on Form 8-K previously filed on October 10, 2006)
3.2	Bylaws of TorreyPines Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the current report on Form 8-K previously filed on October 10, 2006)
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the on Form S-8 previously filed on October 30, 2006)
4.2	Rights Agreement, dated as of May 13, 2005, between Axonyx Inc. and The Nevada Agency and Trust Company, as Rights Agent (incorporated by reference to Exhibit 99.2 to the current report on Form 8-K previously filed by Axonyx Inc. on May 16, 2005)
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-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 15d-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 9, 2006.

TorreyPines Therapeutics, Inc.

By: /s/ Neil M. Kurtz, M.D.

Neil M. Kurtz, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Craig Johnson

Craig Johnson
Vice President, Finance
Chief Financial Officer, and
Secretary
(Principal Financial and Accounting Officer)