TorreyPines Therapeutics, Inc.
Form 10-Q
November 14, 2007

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, 2007

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

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 8, 2007, there were 15,738,485 shares of our Common Stock outstanding.

TorreyPines Therapeutics, Inc.

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PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

TorreyPines Therapeutics, Inc.

Consolidated Balance Sheets

	September 30, 2007 (Unaudited)	December 31, 2006
Assets		
Current assets		
Cash and cash equivalents	$ 39,723,353	$ 55,382,962
Prepaid expenses and other current assets	288,806	581,491
Total current assets	40,012,159	55,964,453
Property and equipment, net	586,786	795,902
Purchased patents, net	3,612,353	3,905,478
Investment in OXIS International, Inc.	2,776,210	2,719,342
Other assets	49,397	49,696
Total assets	$ 47,036,905	$ 63,434,871
Liabilities and stockholders equity		
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,267,405	$ 4,254,265
Long-term debt, current portion	3,476,982	3,200,826
Common stock warrant liability		4,815,000
Total current liabilities	8,744,387	12,270,091
Long-term debt, net of current portion	1,852,019	4,396,649
Deferred revenue	2,083,333	2,183,333
Deferred rent	18,892	15,824
Total liabilities	12,698,631	18,865,897
Commitments and contingencies		
Stockholders equity		
Preferred stock, $0.001 par value, 15,000,000 shares authorized, 0 shares outstanding at September 30, 2007 and December 31, 2006, respectively		
Common stock, $0.001 par value, 150,000,000 shares authorized, 15,737,910 and 15,676,964 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	15,738	15,677
Additional paid-in capital	122,171,363	117,417,003
Accumulated other comprehensive income	396,226	168,301
Accumulated deficit	(88,245,053)	(73,032,007)
Total stockholders equity	34,338,274	44,568,974
Total liabilities and stockholders equity	$ 47,036,905	$ 63,434,871

See accompanying notes.

TorreyPines Therapeutics, Inc.

Consolidated Statements of Operations

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenue				
License and option fees	$ 1,700,000	$ 1,700,000	$ 5,100,000	$ 5,100,000
Research funding	762,500	762,500	2,287,500	2,287,500
Total revenue	2,462,500	2,462,500	7,387,500	7,387,500
Operating expenses:				
Research and development	8,160,942	4,469,639	20,390,016	17,640,251
General and administrative	1,351,162	680,384	4,209,017	1,986,166
Total operating expenses	9,512,104	5,150,023	24,599,033	19,626,417
Loss from operations	(7,049,604)	(2,687,523)	(17,211,533)	(12,238,917)
Other income (expense)				
Interest income	504,290	258,959	1,699,270	732,218
Interest expense	(193,481)	(278,985)	(646,651)	(735,393)
Equity in income (loss) of OXIS International, Inc.	(32,001)		56,867	
Warrant valuation adjustment			892,712	
Gain on asset disposal	(3,711)		(3,711)	2,584
Total other income (expense)	275,097	(20,026)	1,998,487	(591)
Net loss	(6,774,507)	(2,707,549)	(15,213,046)	(12,239,508)
Dividends and accretion to redemption value of redeemable convertible preferred stock		(1,237,082)		(3,533,573)
Net loss attributable to common stockholders	$ (6,774,507)	$ (3,944,631)	$ (15,213,046)	$ (15,773,081)
Basic and diluted net loss per share attributable to common stockholders	$ (0.43)	$ (7.18)	$ (0.97)	$ (29.19)
Weighted average shares used in the computation of basic and diluted net loss per share attributable to common stockholders	15,733,970	549,481	15,711,212	540,395

See accompanying notes.

TorreyPines Therapeutics, Inc.

Consolidated Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2006
Operating activities		
Net loss	$ (15,213,046)	$ (12,239,508)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	287,689	503,639
Stock-based compensation	782,723	79,199
Amortization of debt discount	98,737	81,015
Amortization of purchased patents	293,125	
Deferred rent	3,068	11,509
Deferred revenue	(100,000)	(5,100,000)
Loss (gain) on disposal of assets	3,711	(2,584)
Equity in income of OXIS International, Inc.	(56,867)	
Change in warrant valuation	(892,712)	
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	297,289	122,451
Other assets	299	(2,243,351)
Accounts payable and accrued liabilities	998,777	652,189
Net cash used in operating activities	(13,497,207)	(18,135,441)
Investing activities		
Purchases of property and equipment	(82,284)	(133,483)
Net cash used in investing activities	(82,284)	(133,483)
Financing activities		
Issuance of common stock	49,411	336,091
Issuance of preferred stock, net of issuance costs		6,322,165
Proceeds from long-term debt		5,000,000
Payments on long-term debt	(2,367,211)	(1,359,785)
Net cash provided by (used in) financing activities	(2,317,800)	10,298,471
Effect of exchange rate changes on cash	237,682	237,824
Net decrease in cash and cash equivalents	(15,659,609)	(7,732,629)
Cash and cash equivalents at beginning of period	55,382,962	28,756,888
Cash and cash equivalents at end of period	$ 39,723,353	$ 21,024,259
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 547,914	$ 654,378
Warrant issued in conjunction with debt	$	$ 212,665
Noncash purchases of property and equipment	$	$ 2,584

See accompanying notes.

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TorreyPines Therapeutics, Inc.

Notes to Consolidated Financial Statements

September 30, 2007

(Unaudited)

(1) Basis of Presentation

The accompanying unaudited consolidated financial statements of TorreyPines Therapeutics, Inc. (together with our wholly-owned subsidiaries, TPTX, Inc. and TorreyPines Therapeutics Europe NV) should be read in conjunction with the audited financial statements and notes thereto as of, and for the year ended December 31, 2006 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the SEC). The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles (GAAP) and with the rules and regulations of the SEC related to a quarterly report on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of our management, the accompanying financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair presentation of the financial position, results of operations and cash flows for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

Prior to October 3, 2006 we were known as Axonyx Inc. On October 3, 2006, we completed a business combination, referred to as the Merger, with TorreyPines Therapeutics, Inc. (now known as TPTX, Inc.). For accounting purposes, we were deemed to be the acquired entity in the Merger, and the Merger was accounted for as a reverse acquisition. In connection with the Merger, we changed our name to TorreyPines Therapeutics, Inc. and effected an 8-for-1 reverse stock split of our common stock. Our financial statements reflect the historical results of TPTX, Inc. prior to the Merger and that of the combined company following the Merger, and do not include the historical results of Axonyx Inc. prior to the completion of the Merger. All share and per share disclosures have been retroactively adjusted to reflect the exchange of shares in the Merger, and the 8-for-1 reverse split of our common stock on October 3, 2006. References in this report to TorreyPines, Company, we, us and our refer to TorreyPines Therapeutics, Inc. and its subsidiaries.

(2) Comprehensive Loss

Statement of Financial Accounting Standards (SFAS) No. 130, *Reporting Comprehensive Income,* requires that all components of comprehensive income, including net income or loss and foreign currency translation adjustments, be reported in the financial statements in the period in which they are recognized. Comprehensive income or loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Our comprehensive loss is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net loss	$ (6,774,507)	$ (2,707,549)	$ (15,213,046)	$ (12,239,508)
Foreign currency translation adjustments	158,412	38,308	227,924	237,571
Comprehensive loss	$ (6,616,095)	$ (2,669,241)	$ (14,985,122)	$ (12,001,937)

(3) Net Loss Per Share

We calculate net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the periods presented. Diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding increased to include potentially dilutive common stock equivalents outstanding during the period. For the three- and nine-month periods ended September 30, 2007 and 2006, there is no difference between basic and diluted net loss per share attributable to common stockholders because the effect of common stock equivalents outstanding during the periods, including stock options, restricted stock units, warrants and redeemable convertible preferred stock, is antidilutive.

(4) Eisai Co., Ltd. Agreement

In September 2007 we announced that Eisai Co., Ltd. (Eisai) elected to extend the term of the Cooperation Agreement between TorreyPines and Eisai dated October 1, 2005 for an additional twelve months pursuant to the terms of the agreement. Under the terms of the agreement and in connection with the extension, we received an upfront payment in October 2007 and will continue to receive research funding in support of the program for an additional year.

(5) Common Stock Warrant Liability

During the quarter ended June 30, 2007, we obtained letters from the holders of warrants issued in connection with the Merger clarifying the warrant agreement provisions to allow for settlement of these warrants with the issuance of unregistered shares and to further clarify that a net cash settlement is prohibited. Prior to obtaining the clarification letters, the provisions of the warrant agreement required liability treatment for these instruments under Emerging Issues Task Force Issue No. 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock. On each of the effective dates of these clarification letters (for which we received no additional consideration), the aggregate fair value of $3,922,288 for these warrants, as calculated using the Black-Scholes model, was reclassified from current liabilities to additional paid-in capital and a warrant valuation adjustment of $208,712 was recorded as other income on the accompanying consolidated statement of operations. As of September 30, 2007, the common stock warrant liability was $0.

(6) Commitments and Contingencies

Several lawsuits were filed against us in February 2005 in the U.S. District Court for the Southern District of New York asserting claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act and Rule 10b-5 thereunder on behalf of a class of purchasers of Axonyx 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, M.D., a former director and our former Chief Executive Officer, and Dr. Gosse B. Bruinsma, M.D., also a 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 class action plaintiffs filed an amended consolidated complaint. The Company filed its answer to that complaint on May 26, 2006. The Company s motion to dismiss the consolidated amended complaint was filed on May 26, 2006 and was submitted to the court for a decision in September 2006. The motion to dismiss is pending.

The class action plaintiffs allege generally that the Company s 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 the Company s shares during the class period.

There is also a shareholder derivative suit pending in New York Supreme Court, New York County, against our former directors and officers and one of our current directors. The named defendants are Marvin S. Hausman, M.D., Gosse B. Bruinsma, M.D., S. Colin Neill, Louis G. Cornacchia, Steven H. Ferris, Ph.D., Gerard J. Vlak, Ralph Snyderman, M.D. and Michael A. Griffith. Defendants are alleged to have breached their duties to the Company 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. Management believes the claims are without merit and plans to defend the claims vigorously. The Company has determined that a loss in connection with these matters is possible, but not probable. Accordingly, the Company has not recorded any liability relating to these matters.

(7) Income Taxes

Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities.

The Company has unrecognized tax benefits of approximately $711,000 which did not change significantly during the nine months ended September 30, 2007. The application of FIN 48 would have resulted in a charge to retained earnings of $603,000, except that the charge was fully offset by the application of a valuation allowance. In addition, future changes in the unrecognized tax benefits will have no impact on the effective tax rate due to the existence of the valuation allowance.

As of the date of adoption of FIN 48, no interest or penalties associated with any unrecognized tax benefits were accrued, nor was any interest expense recognized during the quarter. The Company s policy is to record interest and penalties related to tax positions in income tax expense.

The Company is subject to taxation in the United States and various states and foreign jurisdictions. The Company s tax years for 2000 and forward are subject to examination by the United States and various state taxing authorities due to the carryforward of unutilized net operating losses and credits. Tax years 2004 and forward remain open to examination by foreign taxing jurisdictions.

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

This discussion and analysis should be read in conjunction with our unaudited financial statements and notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes as of and for the year ended December 31, 2006 included with our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 29, 2007. Operating results are not necessarily indicative of results that may occur in future periods.

The following discussion of our financial condition contains certain statements that are not strictly historical and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve a high degree of risk and uncertainty. Our actual results may differ materially from those projected in the forward-looking statements due to risks and uncertainties that exist in our operations, development efforts and business environment, including those set forth under the Section entitled Risk Factors in Part II, Item 1A, and other documents we file with the SEC. All forward-looking statements included in this report are based on information available to us as of the date hereof, and, unless required by law, we assume no obligation to update any such forward-looking statement.

Overview

Company Overview

We are a biopharmaceutical company committed to the discovery, development and commercialization of novel small molecules to treat diseases and disorders of the central nervous system, or CNS. Our therapeutic focus is in two areas: chronic pain, including migraine and neuropathic pain; and cognitive disorders, including cognitive impairment associated with schizophrenia and Alzheimer s disease. Through our in-house discovery programs and strategic in-licensing, we have built a robust pipeline of seven product candidates for these indications.

We currently have two product candidates in clinical development for chronic pain. We announced in October 2007 that tezampanel, our lead product candidate for chronic pain, met the primary endpoint in a Phase IIb clinical trial. This clinical trial evaluated the use of tezampanel for the abortive treatment of migraine. We are currently conducting a Phase I clinical trial for our follow-on product candidate for chronic pain, NGX426.

We currently have one product candidate in clinical development for cognitive disorders. NGX267 is our lead product candidate for the treatment of cognitive impairment associated with schizophrenia, or CIAS. We have completed three Phase I clinical trials of NGX267. We expect that NGX267 would be used for the treatment of CIAS as co-therapy to current antipsychotic therapy to treat schizophrenia. In addition, we intend to initiate a small Phase II trial of NGX267 as a potential treatment for dry mouth, or xerostomia, secondary to Sjogren s Syndrome, and we may also evaluate NGX267 for the potential treatment of Alzheimer s disease.

We also have four product candidates in development focused on cognitive disorders: Posiphen® , NGX292, bisnorcymserine and NGX555. Two Phase I clinical trials have been completed for Posiphen. NGX292, bisnorcymserine and NGX555 are currently in preclinical development. In addition, we have two drug discovery programs focused on discovering and validating small molecules and novel molecular targets for Alzheimer s disease, and we are conducting both programs in collaboration with Eisai Co., Ltd., or Eisai, a leader in Alzheimer s disease research.

Recent Developments

In October 2007, we announced that the 40 mg dose of tezampanel demonstrated statistically significant improvement on headache pain response, the primary endpoint, at two hours post-dose compared to placebo in a 306-patient, Phase IIb clinical trial for the treatment of a single, acute migraine attack. Two other doses of tezampanel, 70 mg and 100 mg, were evaluated and also demonstrated effects across a number of pain measurements although neither dose reached statistical significance on the primary endpoint. Although not powered to demonstrate statistical significance, improvement in key secondary measures at 40 mg were either statistically significant or trending when compared to placebo and corroborated the results for the primary endpoint of the study. We intend to submit the data from this trial to the U. S. Food and Drug Administration, or FDA, in order to initiate a Phase III program in acute migraine in the second half of 2008.

In October 2007, we completed the evaluation of NGX426 through the 90 mg dose of our on-going Phase I maximum tolerated, single dose study. We have not reached the maximum tolerated dose of NGX426 and therefore will need to submit an amendment to the FDA to modify the current protocol in order to continue dosing above 90 mg.

In September 2007 we announced that Eisai elected to extend the term of the October 2005 Cooperation Agreement between us and Eisai for an additional twelve months pursuant to the terms of the agreement. Under the terms of the agreement and in connection with the extension, we received an upfront payment in October 2007 and will continue to receive research funding in support of the program for an additional year.

Financial Overview

We have incurred net losses since inception as we have devoted substantially all of our resources to research and development, including early-stage clinical trials. As of September 30, 2007, our accumulated deficit was $88.2 million. We expect to incur substantial and increasing losses for the next several years as we continue to expend resources seeking to successfully research, develop, manufacture, obtain regulatory approval for, and market and sell our product candidates. We expect that in the near term, we will incur substantial losses relating primarily to costs and expenses in our efforts to advance the development of tezampanel, NGX426, and NGX267.

We have not generated any revenue from product sales since inception and do not expect to generate any revenue from product sales for the next several years. Because our product candidates are at an early stage of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Revenue

All of our revenue to date has been derived from license and option fees and research funding from our strategic alliance agreements. We will continue to seek partners for some or all of our product candidates and discovery programs. In the future, we will seek to generate revenue from some or all of the following sources:

- license and option fees from partners;
- research funding from partners;
- milestone payments from partners;
- royalty payments from partners; and
- product sales.

We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of payments received under our strategic alliance agreements, and the amount and timing of payments we receive upon the sale of our products, to the extent any are successfully commercialized. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval, our ability to generate future revenue, and our financial condition and results of operations, would be materially adversely affected.

Research and Development Expense

Since inception, we have focused on discovery and development of novel small molecules to treat CNS diseases and disorders. We currently have four compounds with open Investigational New Drug applications, or INDs, three of which are in clinical trials:

- Tezampanel, for the treatment of migraine, which has been studied in two Phase I clinical trials, five Phase IIa and a Phase IIb clinical trial;
- NGX426, for the treatment of migraine, which has been studied in one Phase I clinical trial and for which we began a Phase I clinical trial in February 2007;
- NGX267, for the treatment of CIAS, which has been studied in two Phase I single dose clinical trials and one Phase I multiple dose clinical trial; and
- Posiphen, for the treatment of Alzheimer s disease, which has been studied in two Phase I clinical trials.

We expense research and development costs as incurred. Research and development expense consists of expenses incurred in identifying, researching, developing and testing product candidates. These expenses primarily consist of the following:

- compensation of personnel associated with research and development activities, including consultants;

fees paid to contract research organizations and professional service providers for independent monitoring, analysis and regulatory services for our clinical trials;

laboratory supplies and materials;

manufacturing of product candidates for use in our preclinical testing and clinical trials;

preclinical studies;

depreciation of equipment; and

allocated costs of facilities and infrastructure.

Because of the risks inherent in research and development, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of our programs, the anticipated completion dates of these programs, or the period in which material net cash inflows are expected to commence, if at all, from the programs described above and any potential future product candidates. If either we or any of our partners fail to complete any stage of the development of any potential products in a timely manner, it could have a material adverse effect on our operations, financial position and liquidity.

General and Administrative Expense

General and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance, accounting, business development, information technology and human resource functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal and accounting services.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments 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 periods. We review our estimates on an ongoing basis, including those related to revenue, accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our management believes the following accounting policies and estimates are most critical to aid you in understanding and evaluating our reported financial results.

Revenue Recognition

We recognize revenue in accordance with the SEC s Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, and Emerging Issues Task Force, or EITF, No. 00-21, *Revenue Arrangements with Multiple Deliverables*. To date we have recorded license and option fee revenue and research funding revenue from four research agreements with Eisai. The terms of the agreements typically include up-front payments to us of non-refundable license and/or option fees and, in some cases, payments for research efforts. Future agreements could also include milestone payments and royalty payments.

We recognize revenue from up-front non-refundable license and option fees on a straight-line basis over the contracted or estimated period of performance, which is typically the research term. Amounts received for research funding for a specific number of full-time researchers are recognized as revenue as the services are provided, as long as the amounts received are not refundable regardless of the results of the research project. Milestone payments, if any, will be recognized on achievement of the milestone, unless the amounts received are creditable against royalties or we have ongoing performance obligations. Royalty payments, if any, will be recognized on sale of the related product, provided the royalty amounts are fixed and determinable, and collection of the related receivable is probable.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services which have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of services for which we must estimate accrued expenses include contract service fees paid to contract manufacturers in conjunction with the production of clinical drug supplies and to contract research organizations in connection with preclinical studies and clinical trials. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided. The majority of our service providers invoice us in arrears for services performed. In the event that we do not identify certain costs which have been incurred, or we under- or over-estimate the level of services performed or the costs of such services in a given period, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us. To date, we have been able to reasonably estimate these costs; however, as we increase the level of services performed on our behalf, it will become increasingly more difficult for us to estimate these costs, which could result in our reported expenses for future periods being too high or too low.

Stock-Based Compensation

We estimate the fair value of stock options and non-performance based restricted stock units granted using the Black-Scholes option valuation model and the fair value of performance based restricted stock units granted using a Monte-Carlo simulation option-pricing model. The fair values of stock option and restricted stock unit awards are amortized over the requisite service periods of the awards. Both the Black-Scholes option valuation model and the Monte-Carlo simulation option-pricing model require the input of highly subjective assumptions, including the option or restricted stock unit s expected life, price volatility of the underlying stock, risk free interest rate and expected dividend rate. As stock-based compensation expense related to stock options is based on awards ultimately expected to vest, the stock-based compensation expense has been reduced for estimated forfeitures of stock options. Statement of Financial Accounting Standards, or SFAS, No. 123R, *Share-Based Payment*, requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock option forfeitures were estimated based on historical experience. We may elect to use different assumptions under both the Black-Scholes option valuation model or the Monte-Carlo simulation option-pricing model in the future, which could materially affect our net income or loss and net income or loss per share.

Recently Issued Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, which provides a single definition of fair value, a framework for measuring fair value, and expanded disclosures concerning fair value. This pronouncement is effective for fiscal years beginning after November 15, 2007. The Company is evaluating the impact of the adoption of SFAS No. 157 will have on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115.* This standard permits an entity to choose to measure many financial instruments and certain other items at fair value. Most of the provisions in SFAS No. 159 are elective; however, the amendment to SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities,* applies to all entities with available-for-sale and trading securities. The fair value option established by SFAS No. 159 permits all entities to choose to measure eligible items at fair value at specified election dates. A business entity will report unrealized gains and losses on items for which the fair value option has been elected in earnings (or another performance indicator if the business entity does not report earnings) at each subsequent reporting date. The fair value option: (a) may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method; (b) is irrevocable (unless a new election date occurs); and (c) is applied only to entire instruments and not to portions of instruments. SFAS No. 159 is effective as of the beginning of an entity s first fiscal year that begins after November 15, 2007. The Company is evaluating the impact the adoption of SFAS No. 159 will have on its consolidated financial statements.

Results of Operations

Fluctuations in Operating Results

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be affected for the foreseeable future by

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several factors, including the timing and amount of payments received pursuant to our current research agreements and future strategic alliance agreements, as well as the progress and timing of expenditures related to our development and discovery efforts. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a good indication of our future performance.

Comparison of the Three Months Ended September 30, 2007 and 2006

The following table summarizes the significant components of our results of operations for the three months ended September 30, 2007 and 2006, in thousands, together with the change in such items in dollars and as a percentage.

	For the Three Months Ended September 30,			
	2007	**2006**	**$ Change**	**% Change**
Revenue	$ 2,463	$ 2,463	$ 0	0%
Research and development expense	8,161	4,470	3,691	83%
General and administrative expense	1,351	680	671	99%
Interest income	504	259	245	95%
Interest expense	193	279	(86)	(31)%

Revenue. Revenue for the three months ended September 30, 2007 was unchanged from the same period in 2006. There were no current quarter changes in our strategic alliance agreements that affected our revenue from license and option fees or research funding.

Research and development expense. Research and development expense increased to $8.2 million for the three months ended September 30, 2007 from $4.5 million for the same period in 2006. The $3.7 million increase was primarily attributable to an increase in development expense which was due to an increase in spending for the development of tezampanel, NGX426 and NGX267 in the three months ended September 30, 2007 compared to the same period in 2006.

General and administrative expense. General and administrative expense increased to $1.4 million for the three months ended September 30, 2007 from $0.7 million for the same period in 2006. The increase was attributable to increased personnel costs and related expenses resulting from an increase in the average number of general and administrative employees during the third quarter of 2007 compared to the same period of 2006. There was also an increase in stock compensation expense during the three months ended September 30, 2007 compared to the same period in 2006. Finally, there was an increase in professional services costs, including increased audit costs, and increased insurance costs during the three months ended September 30, 2007 compared to the same period in 2006.

Interest income. Interest income increased to $504,000 for the three months ended September 30, 2007 from $259,000 for the same period in 2006. The increase of $245,000 was due to a higher average cash and cash equivalents balance during the third quarter of 2007 compared to the third quarter of 2006.

Interest expense. Interest expense decreased to $193,000 for the three months ended September 30, 2007 from $279,000 for the same period in 2006. The $86,000 decrease is attributable to a lower average debt balance during the third quarter of 2007 compared to the third quarter of 2006.

Comparison of the Nine Months Ended September 30, 2007 and 2006

The following table summarizes the significant components of our results of operations for the nine months ended September 30, 2007 and 2006, in thousands, together with the change in such items in dollars and as a percentage.

	For the Nine Months Ended September 30,			
	2007	**2006**	**$ Change**	**% Change**
Revenue	$ 7,388	$ 7,388	$ 0	0%
Research and development expense	20,390	17,640	2,750	16%
General and administrative expense	4,209	1,986	2,223	112%
Interest income	1,699	732	967	132%
Interest expense	647	735	(88)	(12)%

Revenue. Revenue for the nine months ended September 30, 2007 was unchanged from the same period in 2006. There were no current quarter changes in our strategic alliance agreements from period to period that affected our revenue from license and option fees or research funding.

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Research and development expense. Research and development expense increased to $20.4 million for the nine months ended September 30, 2007 from $17.6 million for the same period in 2006. The $2.8 million increase was attributable to an increase in development expense of $4.5 million, offset by a decrease in research expense of $1.7 million.

The $4.5 million increase in development expense was due to our ongoing clinical trials. During the nine months ended September 30, 2007 we had one Phase IIb trial and three Phase I trials in process during the period compared to three Phase I trials during the same period in 2006. Also, during the nine months ended September 30, 2007 activities to support the continued development of tezampanel increased over the same period of 2006. The increase in clinical trial activity is partially offset by a decrease in license costs. During the nine months ended September 30, 2007 we did not achieve any milestones that obligated us to make payments under any of our license agreements. During the nine months ended September 30, 2006 we did achieve certain milestones and therefore were obligated to make certain payments under our agreement with Life Science Research Israel.

The $1.7 million decrease in research expense was primarily due to lower costs incurred under a research agreement with Eisai. Specifically, lower usage of certain lab supplies accounted for most of the decrease. Additionally, there was a decrease in personnel costs and related expenses resulting from a decrease in the average number of research employees during the nine months ended September 30, 2007 compared to the same period in 2006. These decreases were partially offset by an increase in stock compensation expense for the nine months ended September 30, 2007 compared to the same period in 2006.

General and administrative expense. General and administrative expense increased to $4.2 million for the nine months ended September 30, 2007 from $2.0 million for the same period in 2006. The $2.2 million increase was attributable to increased personnel costs and related expenses for the first nine months of 2007 compared to the same period in 2006 resulting from an increase in the average number of general and administrative employees during 2007 compared to 2006. Additionally, for the nine months ended September 30, 2007 stock compensation expense increased for the nine months ended September 30, 2007 compared to the same period of 2006. Finally, there was an increase in professional services costs, including increased audit and legal costs, for the nine months ended September 30, 2007 compared to the same period in 2006.

Interest income. Interest income increased to $1.7 million for the nine months ended September 30, 2007 from $0.7 million for the same period in 2006. The increase of $1.0 million was due to an increase in the average cash and cash equivalents balance during the first nine months of 2007 compared to the same period in 2006.

Interest expense. Interest expense decreased to $647,000 for the nine months ended September 30, 2007 from $735,000 for the same period in 2006. The $88,000 decrease is attributable to a lower average debt balance during the first nine months of 2007 compared to the same period in 2006.

Liquidity and Capital Resources

Since inception we have funded our operations primarily through sales of our equity securities, payments under our research agreements, debt financings and interest income. Through September 30, 2007, we had received approximately $67.5 million in net proceeds from the sale of equity securities, $41.1 million in payments under our research agreements, $18.7 million from debt issuances, and $5.0 million in interest income. In addition, we received $46.5 million of cash in connection with the Merger in October 2006.

At September 30, 2007, we had cash and cash equivalents of $39.7 million as compared to $55.4 million at December 31, 2006. The cash balance at September 30, 2007 is $15.7 million lower than the balance at December 31, 2006 due largely to the current period operating loss, repayments of debt and capital equipment purchases, offset by proceeds from license and option fee payments and research funding payments.

We believe we have sufficient funds to enable us to meet our ongoing working capital requirements through at least December 31, 2008. For a further discussion of the risks related to the availability of cash to fund our future operations, please see Risk Factors.

We expect to continue to fund our operations with existing cash resources that were primarily generated from equity financings, cash payments under our research agreements, and debt financing arrangements until we can generate significant cash from our operations. In addition, we may finance future cash needs through the sale of equity securities, entering into

strategic collaboration agreements and debt financing. However, we may not be successful in entering into strategic collaboration agreements, or in receiving research funding under current agreements or milestone or royalty payments under future agreements. In addition, we cannot be sure that our existing funds will be adequate or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern.

If we raise additional capital by issuing equity securities, our existing stockholders ownership will be diluted. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. In addition, if we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish potentially valuable rights to our product candidates or proprietary technologies, or grant licenses on terms that are not favorable to us.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting mainly of U.S. money market and high-grade corporate securities, directly or through managed funds, with maturities of one and a half years or less. We do not enter into investments for trading or speculative purposes. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10% from levels at September 30, 2007 and 2006, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We have the ability to hold our fixed income investments until maturity therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on its investments.

We have foreign currency accounts that are exposed to currency exchange risk. The functional currency of our European subsidiary, which is based in Belgium, is the local currency. Accordingly, the accounts of this subsidiary are translated from the local currency to the U.S. dollar using the current exchange rate at the balance sheet date for the balance sheet accounts, and using the average exchange rate during the period for revenue and expense accounts. The effects of translation are recorded in accumulated other comprehensive loss as a separate component of stockholders deficit. Because we did not have any transactions denominated in foreign currencies during the three months ended September 30, 2007 and 2006, we did not record exchange gains and losses in operations for those periods. If the foreign currency rates were to fluctuate by 10% from exchange rates at September 30, 2007 and 2006, the effect on our financial statements would not be material. However, there can be no assurance there will be not be a material impact in the future.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a- 15 (e)promulgated under the Exchange Act. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were designed and operating effectively as of the end of the period covered by this Quarterly Report on Form 10-Q.

Our management, including our principal executive officer and our principal financial officer, does not expect that our disclosure controls and procedures or our internal controls 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 control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. 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, if any, within the company have been detected.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2007 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 for the Southern District of New York asserting claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act 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, M.D., a former director and our former Chief Executive Officer, and Dr. Gosse B. Bruinsma, M.D., also a 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 class action plaintiffs 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 was submitted to the court for a decision in September 2006. The motion to dismiss is pending.

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 shareholder derivative suit pending in New York Supreme Court, New York County, against our former directors and officers and one of our current directors. The named defendants are Marvin S. Hausman, M.D., Gosse B. Bruinsma, M.D., S. Colin Neill, Louis G. Cornacchia, Steven H. Ferris, Ph.D., Gerard J. Vlak, Ralph Snyderman, M.D. and Michael A. Griffith. Defendants are alleged to have breached their duties to the company 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 we 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 consider carefully the following information about the risks described below, together with the other information contained in this quarterly report on Form 10-Q and in our other filings with the Securities and Exchange Commission, before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this quarterly report. If any of the following risks actually occur, our business financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock. 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 set forth in our annual report on Form 10-K for the fiscal year ended December 31, 2006, as filed with the Securities and Exchange Commission.

Risks Related to Our Business

We expect to continue to incur net operating losses for the next several years and may never achieve profitability.

We have incurred net operating losses every year since our inception. As of September 30, 2007, we had an accumulated deficit of approximately $88.2 million. Over the next several years we expect a significant increase in our operating losses as we conduct additional discovery, development, clinical testing and regulatory compliance activities. All of our revenue to date has been payments received in connection with our collaboration and licensing agreements. We cannot be certain that we will generate additional revenue through licensing activities or that we will receive any of the milestone or royalty payments associated with our current collaboration and licensing agreements. Given the risks associated with discovery, development, clinical testing, manufacturing and marketing of drug products, we may never be successful in commercializing a drug product that will enable us to be profitable. Our ability to generate significant continuing revenue depends on a number of factors, including:

- successful completion of ongoing and future clinical trials for our product candidates;
- achievement of regulatory approval for our product candidates;
- successful completion of current and future strategic collaborations; and
- successful manufacturing, sales, distribution and marketing of our products.

We do not anticipate that we will generate significant continuing revenue for several years. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

All of our product candidates are at an early stage of development and only a portion of these are in clinical development. We cannot be certain that any of our product candidates will be successfully developed, receive regulatory approval, or be commercialized.

Our product candidates are at an early stage of development and we do not have any products that are commercially available. Our product candidates, tezampanel and NGX426 for migraine, and NGX267 for CIAS are currently in clinical development. Our product candidates Posiphen, NGX292, bisnorcymserine, or BNC, and NGX555 are in preclinical development. We will need to perform additional development work and conduct further clinical trials for all of our product candidates before we can seek the regulatory approvals necessary to begin commercial sales.

Success in preclinical testing and early clinical trials does not mean that later clinical trials will be successful. Companies frequently suffer significant setbacks in later stage clinical trials, even after earlier clinical trials have shown promising results. In future clinical trials with larger or somewhat different populations, results from early clinical trials may not be reproduced and analysis of new or additional data may not demonstrate sufficient safety and efficacy to support regulatory approval of a product candidate.

Additionally, preclinical testing and clinical trials are expensive, can take many years, and have an uncertain outcome. Product candidates may not be successful in clinical trials for a number of reasons, including, but not limited to, the failure of

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a product candidate to be safe and efficacious, the results of later stage clinical trials not confirming earlier clinical results, or clinical trial results not being acceptable to the United States Food and Drug Administration, or FDA, or other regulatory agencies.

There is no certainty that the efficacy and safety results of our Phase IIb clinical trial for tezampanel in acute migraine announced in October 2007 are predictive of results in subsequent trials of tezampanel or are meaningful indicators of the efficacy of tezampanel. We will be required to perform additional clinical testing in order to obtain regulatory approval of tezampanel and the results of such additional clinical testing may not replicate what has been demonstrated to date regarding the efficacy and safety of tezampanel. Additionally, further testing of tezampanel may not result in data sufficient to support regulatory approval.

We do not anticipate that any of our current product candidates will be eligible to receive regulatory approval and begin commercialization for a number of years, if at all. Even if we were to ultimately receive regulatory approval for one or more of our product candidates, we may be unable to successfully commercialize them for a variety of reasons including:

- the availability of alternative treatments;
- the product not being cost effective to manufacture and sell;
- limited acceptance in the marketplace; and
- the effect of competition with other marketed products.

The success of our product candidates may also be limited by the incidence and severity of any adverse events or undesirable side effects. Additionally, any regulatory approval to market a product may be subject to the imposition by such regulatory agency of limitations on the indicated uses. These limitations may reduce the size of the market for the product. If we fail to commercialize one or more of our current product candidates, our business, results of operations, financial condition, and prospects for future growth will be materially and adversely affected.

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.

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 our 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 trial;
- 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 our clinical trials;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious, unexpected adverse events 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 clinical trial participants are being exposed to unacceptable health risks;
- placement by the FDA of a clinical hold on a clinical 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 studies and clinical trials.

In addition, once a clinical trial has started, 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;
- negative clinical trial results;
- adverse events or negative side-effects experienced by the clinical trial participants; or
- lack of adequate funding to continue the clinical trial.

We will need to reach agreement with the FDA on the endpoints for some of our Phase III clinical trials where endpoints have not been validated and we may work with the FDA to potentially design and validate one or more endpoints. The FDA may not accept 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 adequately demonstrate the safety and efficacy of our product candidates would jeopardize our ability to achieve regulatory approval for, and ultimately to commercialize, the product candidates.

Clinical trials require sufficient participant enrollment, which is a function of many factors, including the size of the target population, the nature of the clinical trial protocol, the proximity of participants to clinical trial sites, the availability of effective treatments for the relevant disorder or disease, the eligibility criteria for our clinical trials and the number of competing clinical trials. Delays in enrollment can result in increased costs and longer development times. 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 we may project for any of our 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.

Additionally, 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 lead participants in a clinical trial to discontinue participating in the clinical trial, including, but not limited to: the inclusion of a placebo arm in the clinical 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 by the participant, whether or not related to the product candidate; and the availability of alternative treatment options.

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 product candidates based on similar technologies, are being exposed to unacceptable health risks or for other reasons. 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 and costs will increase. Additionally, any significant delays in the commencement or completion of clinical testing will delay our ability to generate significant revenue.

We rely on third parties to assist us in conducting clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We rely on, and intend to continue to rely on, third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to conduct clinical trials of our product candidates. Our reliance on these third parties for development activities reduces our control over these activities. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe there are a number of third party contractors we could engage to continue these activities, replacing a third party contractor may result in a delay of the affected trial. Accordingly, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

We have licensed rights to product candidates tezampanel and NGX426 from Eli Lilly and Company, or Eli Lilly. Eli Lilly has 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 AK antagonist assets including tezampanel, as well as NGX426. Pursuant to the license agreement 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, 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 Eli Lilly were to terminate the agreement, we would lose rights to the AK antagonist product candidates, and our business would be adversely affected.

We have licensed rights to product candidates NGX267 and NGX292 from Life Science Research Israel, or LSRI. 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. 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 Co. Ltd., or Eisai, for funding for our gamma-secretase modulator program and Alzheimer s disease genetics discovery 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 to treat Alzheimer s disease. The agreement had an initial two-year term which Eisai elected to extend for an additional 12 months. In October 2005, we entered into an agreement with Eisai to discover gene targets useful in treating or preventing Alzheimer s disease in humans. This agreement also has a two-year term which Eisai elected to extend for an additional 12 months. We depend upon Eisai to provide funding for the research we conduct under each of 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 compounds discovered and validated in the course of the gamma-secretase modulator program or gene targets discovered and validated in the course of the Alzheimer s disease genetics research program, as applicable. These rights held by Eisai may delay or limit our ability to enter into a license, collaboration or other arrangement with a third party for any compounds resulting from the gamma-secretase modulator program or gene targets resulting from the Alzheimer s disease genetic research program.

We have an agreement providing Johnson & Johnson Development Corporation, or JJDC, 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 JJDC regarding our research and development work into the effects of using M1 agonists, such as NGX267 and NGX292, 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 both parties, JJDC has the exclusive right of first negotiation with us regarding our intellectual property rights or products related to our M1 agonist program. These rights held by JJDC may delay or limit our ability to enter into a transaction with a third party for our M1 agonist product candidates.

If we fail to enter into and maintain collaborations for our product candidates, we may have to reduce or delay product development or increase expenditures.

Our strategy for developing, manufacturing, and commercializing potential products includes establishing and maintaining collaborations with pharmaceutical and biotechnology companies to advance some of our programs and share expenditures with partners on those programs. We may not be able to negotiate future collaborations on acceptable terms, if at all. If we are not able to establish and maintain collaborative arrangements, we may have to reduce or delay further development of some programs or undertake the development activities at our own expense. If we elect to increase capital expenditures to fund development programs on our own, we will need to obtain additional capital, which may not be available on acceptable terms or at all. Even if we do succeed in securing such collaborations, we may not be able to maintain them if, for example, objectives under the agreement are not met, the agreement is terminated or not renewed, development or approval of a product candidate is delayed or sales of an approved drug are disappointing. Furthermore, any delay in entering into collaborations could delay the development and commercialization of our product candidates and reduce their competitiveness, even if they reach the market. Any such delay related to our collaborations could adversely affect our business.

If our strategic partners do not devote adequate resources to the development and commercialization of our product candidates, we may not be able to commercialize our products and achieve revenues.

We may enter into collaborations with other strategic partners with respect to our product candidates. If we enter into any such collaborations, we may have limited or no control over the amount and timing of resources that our partners dedicate to the development of our product candidates. Our ability to commercialize products we develop with our partners and generate royalties from product sales will depend on the partner s ability to assist us in establishing the safety and efficacy of our product candidates, obtaining regulatory approvals and achieving market acceptance of products. Our partners may elect to delay or terminate development of a product candidate, independently develop products that could compete with our products, or not commit sufficient resources to the marketing and distribution of products under the collaboration. If our partners fail to perform as expected under the collaborative agreements, our potential for revenue from the related product candidates will be dramatically reduced. In addition, revenue from our future collaborations may consist of contingent payments, such as payments for achieving development and commercialization milestones and royalties payable on sales of any successfully developed drugs. The milestone, royalty or other revenue that we may receive under these collaborations will depend upon both our ability and our partner s ability to successfully develop, introduce, market and sell new products. In some cases, we will not be involved in these processes and, accordingly, will depend entirely on our partners.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our 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 discovery and development activities;
- the prioritization and number of clinical development and discovery 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;
- the costs of goods and manufacturing expenses; and
- the costs of establishing or contracting for sales and marketing capabilities.

We do not anticipate that we will generate significant continuing revenue for several years, if at all. Until we can generate significant continuing revenue, if ever, we expect to satisfy our 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 its research and development programs or commercialization efforts.

We do not have internal manufacturing capabilities. If we fail to develop and maintain supply relationships with collaborators or other third party manufacturers, we may be unable to develop or commercialize our products.

Our ability to develop and commercialize our products depends in part on our ability to manufacture, or arrange for future collaborators or other third parties to manufacture, our products at a competitive cost, in accordance with regulatory requirements and in sufficient quantities for clinical testing and eventual commercialization. None of our current product candidates have been manufactured on a commercial scale. We and our third-party manufacturers may encounter difficulties with the small- and large-scale formulation and manufacturing processes required to manufacture our product candidates, resulting in delays in clinical trials and regulatory submissions, in the commercialization of product candidates or, if any product candidate is approved, in the recall or withdrawal of the product from the market. Our inability to enter into or maintain agreements with capable third-party manufacturers on acceptable terms could delay or prevent the commercialization of our products, which would adversely affect our ability to generate revenue and could prevent us from achieving profitability.

We have sufficient supplies of tezampanel, NGX426 and NGX267 for our current clinical trials. We will need to identify and reach agreement with third parties for the supply of our product candidates for future clinical trials. We do not have long-term supply agreements with third parties, and we may not be able to enter into supply agreements with them in a timely manner or on acceptable terms, if at all. These third parties may also be subject to capacity constraints that would cause them to limit the amount of our product candidates they can produce or the chemicals that we can purchase. Any interruption or delay we experience in the supply of our product candidates may impede or delay such product candidates clinical development and cause us to incur increased expenses associated with identifying and qualifying one or more alternate suppliers.

In addition, we, our future collaborators or other third-party manufacturers of our products must comply with current Good Manufacturing Practices, or cGMP, requirements enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. In addition, product manufacturing facilities in California are subject to licensing requirements of the California Department of Health Services and may be inspected by the California Department of Health Services at any time. We, our collaborators or other third-party manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval.

We currently have no marketing or sales staff. If we are unable to enter into or maintain collaborations with marketing partners or if we are unable to develop our own sales and marketing capabilities, we may not be successful in commercializing our potential products and we may be unable to generate significant revenues.

We may elect to commercialize some of the products we are developing on our own, with or without a partner, where those products can be effectively marketed and sold in concentrated markets that do not require a large sales force to be competitive. We currently have no sales, marketing or distribution capabilities. To be able to commercialize our own products, we will need to establish our own specialized sales force and marketing organization with technical expertise and

with supporting distribution capabilities. Developing such an organization is expensive and time consuming and could delay or limit our ability to commercialize products.

To commercialize any product candidate that we decide not to market on our own, we will depend on collaborations with third parties that have established distribution systems and direct sales forces. If we are unable to enter into such collaborations on acceptable terms, we may not be able to successfully commercialize those products.

To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenue is likely to be lower than if we directly marketed and sold our product candidates. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenue and may not become profitable and the price of our common stock may be negatively affected.

Tezampanel, NGX426 and NGX555 belong to new classes of compounds. There are no compounds in these classes that have received regulatory approval for any indication. Therefore, we do not know whether our product candidates will yield commercially viable products or receive regulatory approval.

Tezampanel and NGX426 are antagonists of the AK receptors. They are part of a new class of compounds that block the AK receptors and, in turn, stop the transmission of pain signals. These product candidates may represent a novel approach to the management of chronic pain, including migraine and neuropathic pain. There are currently no approved products for chronic pain that are AK antagonists. As a result, we cannot be certain that our product candidates will result in commercially viable drugs that safely and effectively treat chronic pain indications such as migraine or neuropathic pain.

NGX555, a gamma-secretase modulator, is a product candidate for Alzheimer s disease. This product candidate belongs to a class of compounds that have been studied, or are being studied, as a treatment for Alzheimer s disease, but there are no approved gamma-secretase modulator products for Alzheimer s disease. As a result, we cannot be certain that our product candidates will safely and effectively improve the symptoms of Alzheimer s disease or modify the progression of the disease or result in commercially viable drugs.

NGX267 and NGX292 are being developed for CIAS, an indication for which there are no products approved by the FDA to treat the disorder, and for which no regulatory precedents have been established. Therefore, we do not know whether our product candidates will yield commercially viable products or receive regulatory approval.

NGX267 and NGX292 are muscarinic agonists with functionally specific M1 receptor activity that we intend to develop for the treatment of CIAS. There are currently no approved therapies for the treatment of CIAS. Therefore, in order to successfully commercialize our product candidates, we will need to agree with the FDA and other applicable regulatory agencies on clinical trial endpoints regarding safety and efficacy. Given the lack of current treatments for CIAS, we may be unable to agree on the endpoints or successfully complete clinical trials that demonstrate that such endpoints, if agreed to, have been met. Any delay in agreeing to clinical trial endpoints or in achieving those endpoints will prevent us from commercializing our product candidates.

If our product candidates do not achieve market acceptance among physicians, patients, health care payors and the medical community, they will not be commercially successful and our business will be adversely affected.

The degree of market acceptance of any of our approved product candidates among physicians, patients, health care payors and the medical community will depend on a number of factors, including:

- acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing and cost effectiveness;

- effectiveness of sales and marketing strategies; and

- ability to obtain sufficient third-party coverage or reimbursement.

If we are unable to achieve market acceptance for our product candidates, then such product candidates will not be commercially successful and our business will be adversely affected.

If our efforts to discover new product candidates do not succeed, and product candidates that we recommend for clinical development do not actually begin clinical trials, our business will suffer.

We intend to use our expertise in Alzheimer s disease and related neurodegenerative diseases and disorders to discover, develop and commercialize new products for the treatment and prevention of these diseases and disorders. Once advanced into development, a product candidate undergoes drug substance scale up, preclinical testing, including toxicology tests, and formulation development. If this work is successful, an IND would need to be prepared, filed, and approved by the FDA and the product candidate would then be ready for human clinical testing.

The process of discovering and conducting preclinical testing on product candidates is expensive, time-consuming and unpredictable. If we are unable to advance our product candidates to clinical trials our business will be adversely affected.

If we fail to attract and keep key management and scientific personnel, we may be unable to develop or commercialize our product candidates successfully.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. The loss of the services of any principal member of our senior management could delay or prevent the commercialization of our product candidates. We employ these individuals on an at-will basis and their employment can be terminated by us or them at any time, for any reason and with or without notice, subject to the terms contained in their respective employment agreements and offer letters.

Competition for qualified personnel in the biotechnology field is intense. We may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies.

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

Licensing our 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. Our partners who created these product candidates are experienced 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 drug products from our discovery program is likely to attract additional research by our licensors in addition to other investigators who have experience in developing products for the CNS 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.

Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting charges or require us to change our compensation policies.

Accounting methods and policies for biopharmaceutical companies, including policies governing revenue recognition, expenses, accounting for stock options and in-process research and development costs are subject to further review, interpretation and guidance from relevant accounting authorities, including the SEC. Changes to, or interpretations of, accounting methods or policies in the future may result in unfavorable accounting charges or may require us to change our compensation policies to avoid such charges.

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. 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 corporate governance practices. Our management and other personnel will have to meet these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs 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

our 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.

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 was filed against us, as described under Part II, 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. We have purchased liability insurance, however, if any costs or expenses associated with the litigation exceed the insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial and may have an adverse effect on our business, financial condition, results of operations and cash flows. 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.

Fluctuations in currency exchange rates may negatively impact our business.

We currently have operations in Belgium and are conducting clinical trials in Europe. Costs resulting from our operations in Europe are denominated primarily in local currencies, including the Euro, and are subject to fluctuations in currency exchange rates. Further, we incur other operating expenses, including expenses related to clinical trials, which are denominated in Euros and other local currencies. Significant fluctuations in the currency exchange rates and general economic conditions in the countries in which we do business, could harm our operating results.

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

We account 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 carrying value was permanent.

Risks Related to Our Intellectual Property

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 our patents against third-party challenges. We will only be able to protect our 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 our 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 our 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, it 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 its 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 our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Industry

Our product candidates are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, future advertising, promotion, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable foreign governmental authorities. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the products involved. Approval policies or regulations may change. In addition, although members of our management have drug development and regulatory experience, as a company we have not previously filed the marketing applications necessary to gain regulatory approvals for any product. This lack of experience may impede our ability to obtain FDA marketing approval in a timely manner, if at all, for the product candidates we are developing and commercializing. We will not be able to commercialize our product candidates in the U.S. until we obtain FDA approval and in other countries until we obtain approval by comparable governmental authorities. Any delay in obtaining, or inability to obtain, these approvals would prevent us from commercializing our product candidates.

Even if any of our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

If any of our product candidates receive regulatory approval, the FDA and foreign regulatory authorities may still impose significant restrictions on the uses or marketing of the product candidates or impose ongoing requirements for post-approval studies. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer s facilities to continuing review and periodic inspections. If previously unknown problems with a product or its manufacturing facility are discovered, a regulatory agency may impose restrictions on that product, us, or our partners, including requiring withdrawal of the product from the market. Our candidates will also be subject to ongoing FDA requirements for submission of safety and other post-market information. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

issue warning letters;

impose civil or criminal penalties;

suspend regulatory approval;

- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

In order to market any products outside of the U.S., we and our partners must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects described above regarding FDA approval in the U.S., including the risk that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and adversely impact potential royalties and product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we and our partners fail to comply with applicable foreign regulatory requirements, we and our partners may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

If our competitors have products that are approved faster, marketed more effectively or demonstrated to be more effective than our products, then our commercial opportunity will be reduced or eliminated.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Due to the high demand for treatments for CNS diseases and disorders, research is intense and new treatments are being sought out and developed by our competitors.

In addition, many other competitors are developing products for the treatment of the diseases we are targeting and if successful, these products could compete with our products. If we receive approval to market and sell any of our product candidates, we may compete with these companies and their products as well as others in varying stages of development.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than ours, or that would render our product candidates obsolete and noncompetitive. Our competitors may succeed in obtaining approvals from the FDA and foreign regulatory authorities for their products sooner than we do. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

We are subject to uncertainty relating to health care reform measures and reimbursement policies which, if not favorable to our product candidates, could hinder or prevent the commercial success of our product candidates.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect our:

- ability to set a price we believe is fair for our products;
- ability to generate revenues and achieve profitability;
- future revenues and profitability of potential customers, suppliers and collaborators; and

the availability of capital.

In certain foreign markets, the pricing of prescription drugs is subject to government control. In the U.S., given recent federal and state government initiatives directed at lowering the total cost of health care, Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription drugs and the reform of the Medicare and Medicaid systems. For example, a new Medicare prescription drug benefit program began in 2006. While we cannot predict the full outcome of the implementation of this legislation or whether any future legislative or regulatory proposals affecting our business will be adopted, the announcement or adoption of these proposals could materially and adversely affect our business, financial condition, and results of operations.

Our ability to commercialize our product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of our products and related treatments. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the U.S., which could significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for our product candidates or exclusion of its product candidates from reimbursement programs. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially and adversely affect our results of operations.

Product liability claims may harm our business if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and will face an even greater risk if we sell our product candidates commercially. An individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product candidates.

We have product liability insurance that covers our clinical trials, up to an annual aggregate limit of $5.0 million. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

We use hazardous chemicals and radioactive and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time-consuming and costly.

Our research and development processes involve the controlled use of hazardous materials, including chemicals, radioactive and biological materials. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from those materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

Risks Related to our Common Stock

Our stock price has been, and is expected to continue to be, volatile.

The market price of our common stock could be subject to significant fluctuations. 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 our 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;
- 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;
- failure of any of our product candidates, if approved, to achieve commercial success;
- 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.

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.

Our largest stockholders may take actions that are contrary to your interests, including selling their stock.

A small number of our stockholders hold a significant amount of our outstanding stock. These stockholders may support competing transactions and have interests that are different from yours. In addition, the average number of shares of our stock that trade each day is generally low. As a result, sales of a large number of shares of our stock by these large stockholders or other stockholders within a short period of time could adversely affect our stock price.

Our management has broad discretion over the use of our cash and we may not use our cash effectively, which could adversely affect our results of operations.

Our management has significant flexibility in applying our cash resources and could use these resources for corporate purposes that do not increase our market value, or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

Raising additional funds by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders, restrict operations or require us to relinquish proprietary rights.

We may raise additional funds through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. To the extent that we raise additional capital by issuing equity securities, our existing stockholders ownership will be diluted. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem stock or make investments. In addition, if we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us.

There is only a limited trading market for our common stock and it is possible that investors may not be able to sell their shares easily.

There is currently only a limited trading market for our common stock. Our common stock trades on the Nasdaq Global Market under the symbol TPTX with very limited trading volume. We cannot assure investors that a substantial trading market will be sustained for our common stock.

Item 6. Exhibits

Number	Exhibits
2.1	Agreement and Plan of Merger and Reorganization, dated as of June 7, 2006, by and among Axonyx Inc., Autobahn Acquisition, Inc. and TorreyPines Therapeutics, Inc. (incorporated by reference to Annex A to Registration Statement No. 333-136018 filed with the Securities and Exchange Commission on July 25, 2006).
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated as of August 25, 2006, by and among Axonyx Inc., Autobahn Acquisition, Inc. and TorreyPines Therapeutics, Inc. (incorporated by reference to Annex A to Amendment No. 1 to Registration Statement No. 333-136018 filed with the Securities and Exchange Commission on August 25, 2006).
3.1	Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on October 10, 2006).
3.2	Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K, filed on October 10, 2006).
3.3	Certificate of Amendment filed with the Secretary of State of the State of Nevada effecting an 8-for-1 reverse stock split of the Registrant s common stock and changing the name of the Registrant from Axonyx Inc. to TorreyPines Therapeutics, Inc. (incorporated by reference to Exhibit 3.3 to the Registrant s Current Report on Form 8-K, filed on October 10, 2006).
3.4	Articles of Conversion filed with the Secretary of State of the State of Nevada changing the state of incorporation of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant s Current Report on Form 8-K, filed on October 10, 2006).
3.5	Certificate of Conversion filed with the Secretary of State of the State of Delaware (incorporated by reference to Exhibit 3.5 to the Registrant s Current Report on Form 8-K, filed on October 10, 2006).
3.6	Amendment to Bylaws of the Registrant (incorporated by reference to Exhibit 3.6 to the Registrant s Annual Report on Form 10-K, filed on March 29, 2007).
4.1	Specimen common stock certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant s Quarterly Report on Form 10-Q, filed on August 14, 2007).
4.2	Form of Warrant to Purchase Common Stock issued to previous holders of TPTX, Inc. redeemable convertible preferred stock in connection with the business combination between TorreyPines Therapeutics, Inc. and Axonyx, Inc. (incorporated by reference to Exhibit 4.2 to the Registrant s Annual Report on Form 10-K, filed on March 29, 2007).
4.3	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.3 to Registrant s Annual Report on Form 10-KSB filed on March 13, 2000).
4.4	Form of Registration Rights Agreement 1999 (incorporated by reference to Exhibit 4.4 to the March 13, 2000 10-KSB).
4.5	Form of Warrant issued to Stonegate Securities (incorporated by reference to the corresponding exhibit to Registrant s Annual Report on Form 10-KSB filed on March 22, 2001).
4.6	Form of Common Stock Purchase Warrant issued to purchasers in a private placement on December 6, 2001 (incorporated by reference to Exhibit 10.2 to Registrant s Current Report on Form 8-K filed on December 13, 2001).
4.7	Form of Warrant issued to SCO Financial Group, LLC (incorporated by reference to exhibit 4.5 to Registrant s Registration Statement on Form S-3 (File No. 333-76234) filed on January 3, 2002).
4.8	Form of Common Stock Purchase Warrant issued to purchasers in a private placement on January 6, 2003 (incorporated by reference to Exhibit 10.2 in Registrant s Current Report on Form 8-K filed on January 8, 2003).

Number	Exhibits
4.9	Form of Warrant issued to AFO Advisors, LLC (incorporated by reference to Exhibit 4.2 in Registrant s registration statement on Form S-3 (File No. 333-103130) filed on February 12, 2003).
4.10	Form of Common Stock Purchase Warrant issued to purchasers in a private placement on September 12, 2003 (incorporated by reference to Exhibit 10.2 in Registrant s Current Report on Form 8-K filed on September 16, 2003).
4.11	Form of Common Stock Purchase Warrant issued to purchasers in a private placement on January 8, 2004 (incorporated by reference to Exhibit 4.3 in Registrant s Current Report on Form 8-K filed on January 12, 2004).
4.12	Registration Rights Agreement dated as of January 8, 2004 between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.2 in the current report on Form 8-K previously filed by Axonyx Inc. on January 12, 2004)
4.13	Registration Rights Agreement dated as of May 3, 2004, between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.2 in the current report on Form 8-K previously filed by Axonyx Inc. on May 5, 2004)
4.14	Form of Warrant issued to Comerica Bank on July 1, 2003 (incorporated by reference to Exhibit 4.14 to the Registrant s Annual Report on Form 10-K, filed on March 29, 2007).
4.15	Form of Warrant issued to Silicon Valley Bank on December 8, 2000 (incorporated by reference to Exhibit 4.15 to the Registrant s Annual Report on Form 10-K, filed on March 29, 2007).
4.16	Form of Warrant issued to Oxford Financial and Silicon Valley Bank on September 27, 2005 (incorporated by reference to Exhibit 4.16 to the Registrant s Annual Report on Form 10-K, filed on March 29, 2007).
4.17	Rights Agreement, dated as of May 13, 2005, between the Registrant and American Stock Transfer and Trust Company (replacing Nevada Agency and Trust Company), as Rights Agent (incorporated by reference to Exhibit 99.2 to the Registrant s Current Report on Form 8-K, filed on May 16, 2005).
4.18	Amendment to Rights Agreement, dated as of June 7, 2006, between the Registrant and American Stock Transfer and Trust Company (replacing Nevada Agency and Trust Company), as Rights Agent (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K, filed on June 12, 2006).
4.19	Amendment to Rights Agreement, dated as of October 3, 2006, between the Registrant and American Stock Transfer and Trust Company (replacing Nevada Agency and Trust Company), as Rights Agent (incorporated by reference to Exhibit 4.19 to the Registrant s Annual Report on Form 10-K, filed on March 29, 2007).
4.20	Reference is made to Exhibits 3.1 through 3.6.
31.1	Certification of Principal 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 Principal Financial and Accounting 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 Principal 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 Principal Financial and Accounting 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.

Date: November 14, 2007

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)