TorreyPines Therapeutics, Inc.
Form 10-Q
May 01, 2009
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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 March 31, 2009

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number: 000-25571

TORREYPINES THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨.

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 ¨	Accelerated filer ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of April 28, 2009, there were 15,999,058 shares of our Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

TorreyPines Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	March 31, 2009 (Unaudited)	December 31, 2008
Assets		
Current assets		
Cash and cash equivalents	$ 6,319	$ 10,864
Prepaid expenses and other current assets	379	187
Total current assets	6,698	11,051
Property and equipment, net	11	40
Other assets		39
Total assets	$ 6,709	$ 11,130
Liabilities and stockholders equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 1,681	$ 3,865
Long-term debt, current portion	3,197	1,440
Total current liabilities	4,878	5,305
Long-term debt, net of current portion		2,112
Total liabilities	4,878	7,417
Commitments and contingencies		
Stockholders equity		
Preferred stock, $0.001 par value, 15,000,000 shares authorized, 0 shares outstanding at March 31, 2009 and December 31, 2008, respectively		
Common stock, $0.001 par value, 150,000,000 shares authorized, 15,974,058 and 15,974,058 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	16	16
Additional paid-in capital	123,121	122,883
Accumulated deficit	(121,306)	(119,186)
Total stockholders equity	1,831	3,713
Total liabilities and stockholders equity	$ 6,709	$ 11,130

See accompanying notes.

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TorreyPines Therapeutics, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

(Unaudited)

	Three months ended March 31,	
	2009	**2008**
Revenue		
License and option fees	$	$ 1,283
Research funding		763
Total revenue		2,046
Operating expenses		
Research and development	855	5,260
General and administrative	1,268	1,448
Total operating expenses	2,123	6,708
Loss from operations	(2,123)	(4,662)
Other income (expense)		
Interest income	8	217
Interest expense	(45)	(147)
Other income (expense), net	40	699
Total other income (expense)	3	769
Net loss	(2,120)	(3,893)
Basic and diluted net loss per share	$ (0.13)	$ (0.25)
Weighted average shares used in the computation of basic and diluted net loss per share	15,974,058	15,739,646

See accompanying notes.

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TorreyPines Therapeutics, Inc.

Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Three months ended March 31,	
	2009	**2008**
Operating activities		
Net loss	$ (2,120)	$ (3,893)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	14	76
Stock-based compensation	238	180
Amortization of debt discount	9	33
Amortization of purchased patents		98
Deferred revenue		(1,283)
Gain on disposal of assets	(43)	
Change in fair value of investment in OXIS International, Inc.		(699)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(142)	296
Other assets	35	(4)
Accounts payable and accrued liabilities	(2,184)	(997)
Net cash used in operating activities	(4,193)	(6,193)
Investing activities		
Proceeds from sale of property and equipment	8	
Net cash used in investing activities	8	
Financing activities		
Issuance of common stock		7
Payments on long-term debt	(360)	(857)
Net cash used in financing activities	(360)	(850)
Effect of exchange rate changes on cash		208
Net decrease in cash and cash equivalents	(4,545)	(6,835)
Cash and cash equivalents at beginning of period	10,864	32,500
Cash and cash equivalents at end of period	$ 6,319	$ 25,665
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 36	$ 184

See accompanying notes.

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TorreyPines Therapeutics, Inc.

Notes to Consolidated Financial Statements

March 31, 2009

(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, 2008 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the SEC) on March 27, 2009. 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. References in this report to TorreyPines, Company, we, us and our refer to TorreyPines Therapeutics, Inc. and its subsidiaries.

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.

(2) Going Concern Considerations

As of March 31, 2009 our accumulated deficit was $121.3 million and based on our operating plan, our existing working capital is not sufficient to meet our cash requirements to fund our planned operating expenses and working capital requirements through December 31, 2009 without additional sources of cash.

These conditions raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business.

Our management plans to address the expected shortfall of working capital by securing additional funding through project financing, equity financing, a development partner or sale of assets. Additionally, we have been and are continuing to explore other strategic alternatives, including a possible asset out-licensing, asset sale or sale of the Company. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures. There can be no assurance that we will be able to obtain any sources of funding.

If we cannot obtain sufficient funding in the short-term, we may be forced to file for bankruptcy, cease operations or liquidate and dissolve the Company. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we be forced to take such actions.

(3) Reduction-in-Force

In an effort to conserve financial resources, on March 31, 2009 we reduced our work force to three employees. In connection with the reduction-in-force, a restructuring charge of $191,000 was recorded in the three months ended March 31, 2009. The restructuring charge is included in operating expenses in the statement of operations and is comprised of $85,000 of research and development expense and $106,000 of general and administrative expense.

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(4) Comprehensive Loss

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 (amounts in thousands):

	Three Months Ended March 31,	
	2009	2008
Net loss	$ (2,120)	$ (3,893)
Foreign currency translation adjustments		210
Comprehensive loss	$ (2,120)	$ (3,683)

(5) Net Loss Per Share

We calculate net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. Net loss per share is computed on the basis of the weighted-average number of shares of common stock outstanding during the periods presented. Net loss per share assuming dilution is computed on the basis of the weighted-average number of common shares outstanding and the dilutive effect of all common stock equivalents. For the three-month periods ended March 31, 2009 and 2008, 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 and warrants, is antidilutive.

(6) Note Payable

In June 2008 we entered into a note agreement to borrow $3.6 million. Because the note was paid in full shortly after March 31, 2009 (see Note 8), we have classified the entire balance of the note payable, net of the unamortized debt discount of $43,000, as a current liability as of March 31, 2009. Additionally, the unamortized debt issuance costs of $35,000 were classified as a current asset as of March 31, 2009.

(7) 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 director and our 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. On March 31, 2009 the U.S. District Court for the Southern District of New York dismissed the proceedings. On April 24, 2009 an appeal was filed with the United States Court of Appeals for the Second Circuit by the class action plaintiffs.

(8) Subsequent Event

Pursuant to the terms of our note agreement, we are required to maintain a cash balance with the lender s bank of at least $5.4 million. As of March 31, 2009, our entire cash balance of $6.3 million is deposited with the lender. Although our cash balance as of March 31, 2009 exceeds the lender s minimum cash balance of $5.4 million, it was determined that our cash balance would drop below $5.4 million before the end of April 2009. We chose to repay the outstanding balance of the note in April 2009 just prior to our cash balance dropping below $5.4 million. On April 23, 2009 we repaid the note in full. The total payoff of the note was $3.1 million.

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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, 2008 included with the our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 27, 2009. 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 providing patients with better alternatives to existing therapies through the development and commercialization of small molecule compounds. Our goal is to develop versatile product candidates each capable of treating a number of acute and chronic diseases and disorders such as migraine, acute and chronic pain, and xerostomia. Due to the Company s current financial condition as described further in this report, we have been and are continuing to explore financing and strategic alternatives, including a possible project financing, equity financing, or a partnership in order to continue the development of our three product candidates, two ionotropic glutamate receptor antagonists and one muscarinic receptor agonist. Additionally, we have been and are continuing to explore other strategic alternatives, including a possible asset out-licensing, asset sale or sale of the Company. If we are unable to complete a financing or strategic transaction during the first half of 2009, we will be unable to continue as a going concern and may be forced to file for bankruptcy, cease operations or liquidate and dissolve the Company.

Our two ionotropic glutamate receptor antagonists, tezampanel and NGX426, are clinical stage product candidates. Tezampanel and NGX426 competitively block the binding of glutamate at the glutamate receptors, specifically the AMPA and kainate receptor subtypes. While normal glutamate levels are essential, excess glutamate has been implicated in a number of diseases and disorders. Tezampanel and NGX426 are the first glutamate receptor antagonists with this combined binding activity to be tested in humans. In October 2007 we released the results of a Phase IIb clinical trial of tezampanel, our most advanced product candidate. In this clinical trial, a single dose of tezampanel given by injection was statistically significant compared to placebo in treating acute migraine headache. This was the sixth Phase II trial in which tezampanel has been shown to have analgesic activity. We held a successful end of Phase II meeting with the U.S. Food and Drug Administration (FDA) on September 29, 2008. Based on a review of the Phase II data, the FDA agreed that we may initiate a Phase III program for tezampanel in acute migraine. The FDA also confirmed that the required thorough QT/QTc study for tezampanel can be conducted in parallel with the first Phase III pivotal trial. In order to pursue further clinical development of tezampanel, including the initiation of a Phase III trial, we will need to secure project financing, equity financing, or a development partner.

NGX426 is an oral prodrug of tezampanel. In clinical trials, NGX426 has been shown to rapidly convert to tezampanel. During 2008 we completed a Phase I clinical trial that was designed to identify the maximum tolerated single dose of NGX426 when given to healthy adults. Subjects were dosed up to 210 mg, the maximum dose allowable under the protocol. All doses were safe and well tolerated therefore the maximum tolerated dose was not reached. In December 2008 we announced that oral administration of a single dose of NGX426 to healthy male adults demonstrated a statistically significant reduction in spontaneous pain, hyperalgesia (abnormally increased pain state) and allodynia (pain resulting from normally non-painful stimuli to the skin) compared to placebo following injection under the skin of capsaicin in an experimental model of induced pain, hyperalgesia and allodynia. In February 2009 we announced that oral administration of NGX426 was safe and well-tolerated in healthy male and female subjects when dosed once daily for five consecutive days. In order to pursue further clinical development of NGX426 we will need to secure project financing, equity financing, or a development partner.

NGX267 is a muscarinic agonist. We have completed three Phase I clinical trials evaluating single and multiple doses of NGX267 given to healthy adults. In December 2008, we announced positive results from a 26 patient Phase II trial evaluating three doses of NGX267 as a potential treatment for xerostomia, or dry mouth, in patients with Sjögren s syndrome. All three doses of NGX267 met the primary endpoint of a statistically significant increase in salivary flow production compared to placebo. These doses were safe and well tolerated. In order to pursue further clinical development of NGX267 we will need to secure project financing, equity financing, or a development partner.

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We also have one drug discovery program, a gamma-secretase modulator program. We are currently attempting to sell this program.

In an effort to conserve financial resources, on March 31, 2009 we reduced our work force to three employees. In addition to our efforts to sell our GSM program in 2009 we continue to explore project financing, equity financing, partnership opportunities, asset out-licensing, or an asset sale for tezampanel, NGX426 and NGX267 to enable us to pursue the commercial opportunities we have identified for these product candidates. In addition we continue to explore opportunities to sell the Company as a whole. However, if we are unable to complete a financing or strategic transaction in the first half of 2009, we will be unable to continue as a going concern and may be forced to file for bankruptcy, cease operations or liquidate and dissolve the Company.

Going Concern and Management s Plan

Our independent registered public accounting firm included an explanatory paragraph in their report on our 2008 financial statements related to the uncertainty and substantial doubt of our ability to continue as a going concern.

We have incurred net losses since inception and as of March 31, 2009 have an accumulated deficit of $121.3 million. Based on our operating plan, our existing cash and cash equivalents will only fund our operations into the second quarter, and possibly into the third quarter, of 2009. These conditions raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business.

Our management plans to address the expected shortfall of working capital by securing additional funding through project financing, equity financing, a development partner or the sale of assets. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures. There can be no assurance that we will be able to obtain any sources of funding.

If we cannot obtain sufficient funding in the short-term, we may be forced to file for bankruptcy, cease operations or liquidate and dissolve the Company. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we be forced to take any such actions.

Financial Overview

Revenue

All of our revenue to date has been derived from license and option fees, research funding from our strategic alliance agreements or the sale of a research program. We will continue to seek partners or acquirers for all of our product candidates and our remaining drug discovery program.

Research and Development

Since inception, we have focused on discovery and development of novel small molecule compounds to treat a number of acute and chronic diseases and disorders.

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 and consultants associated with research and development activities;
- 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

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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

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.

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 several factors, including the timing and amount of payments received pursuant to any future strategic alliance agreements, as well as the progress and timing of expenditures related to our development 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 March 31, 2009 and 2008

The following table summarizes the significant components of our results of operations for the three months ended March 31, 2008 and 2007, in thousands, together with the change in such items in dollars and as a percentage.

	For the Three Months Ended March 31,			
	2009	**2008**	**$ Change**	**% Change**
Revenue	$	$ 2,046	$ (2,046)	(100)%
Research and development expense	855	5,260	(4,405)	(84)%
General and administrative expense	1,268	1,448	180	(12)%
Interest income	8	217	(209)	(96)%
Interest expense	45	147	(102)	(69)%

Revenue. Revenue decreased to $0 for the three months ended March 31, 2009 from $2.0 million for the same period in 2008. The decrease of $2.0 million was due to the conclusion of our GSM collaboration with Eisai Co., Ltd., or Esai, in February 2008. We have not entered into any new collaborations, therefore during the quarter ended March 31, 2009 we did not recognize any revenue. During 2008 in connection with the GSM collaboration with Eisai, we recognized revenue for two months of the quarter ended March 31, 2008.

Research and development expense. Research and development decreased to $0.9 million for the three months ended March 31, 2009 from $5.3 million for the same period in 2008. The $4.4 million decrease was attributable to a decrease in research expense of $1.7 million and a decrease in development expense of $2.7 million.

The decrease in research expense is due to the conclusion of our GSM collaboration agreement with Eisai in February 2008 and the conclusion of our Alzheimer s disease genetics collaboration agreement with Eisai in September 2008. In September 2008 we initiated a strategic restructuring under which we transitioned from a discovery and development company to a development-only company. As a result, we did not incur research expenses during the three months ended March 31, 2009.

During the first quarter of 2009 we had no ongoing clinical development studies. The decrease in development expense is the result of a lack of working capital and is specifically due to decreased clinical development activities for tezampanel, NGX424 and NGX267 in the three months ended March 31, 2009 compared to the same period of 2008.

General and administrative expense. General and administrative expense decreased to $1.3 million for the three months ended March 31, 2009 from $1.4 million for the same period in 2008. The $0.1 million decrease was due to decreased personnel costs and related expenses and decreased professional services costs, offset by an increase in stock based compensation expense for the three months ended March 31, 2009 compared to the same period of 2008.

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Interest income. Interest income decreased to $8,000 for the three months ended March 31, 2009 from $217,000 for the same period in 2008. The decrease of $209,000 was due to a lower average cash and cash equivalents balance during the first quarter of 2009 compared to the first quarter of 2008.

Interest expense. Interest expense decreased to $45,000 for the three months ended March 31, 2009 from $147,000 for the same period in 2008. The $102,000 decrease is attributable to a lower average debt balance and a lower interest rate during the first quarter of 2009 compared to the first quarter of 2008.

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 March 31, 2009, we had received approximately $68.0 million in net proceeds from the sale of equity securities, $47.4 million in payments under our research agreements, $22.4 million from debt issuances, and $5.5 million in interest income. In addition, as a result of a business combination we completed in October 2006, we received $46.5 million of cash.

At March 31, 2009, we had cash and cash equivalents of $6.3 million as compared to $10.9 million at December 31, 2008. The cash balance at March 31, 2009 is $4.6 million lower than the balance at December 31, 2008 due largely to the current quarter operating loss and repayments of debt.

We believe we have sufficient funds to enable us to meet our ongoing working capital requirements through at least June 30, 2009. For a further discussion of the risks related to the availability of cash to fund our future operations, please see Risk Factors.

We have been and are continuing to explore financing and strategic alternatives, including a possible project financing, equity financing, or a partnership in order to continue the development of our three product candidates, two ionotropic glutamate receptor antagonists and one muscarinic receptor agonist. Additionally, we have been and are continuing to explore other strategic alternatives, including a possible asset out-licensing, asset sale or sale of the Company. If we are unable to complete a financing or strategic transaction during the first half of 2009, we will be unable to continue as a going concern and may be forced to file for bankruptcy, cease operations or liquidate and dissolve the Company.

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.

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.

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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 granted using the Black-Scholes option valuation model and the fair value of 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.

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. If market interest rates were to increase immediately and uniformly by 10% from levels at March 31, 2009 and 2008, 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.

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Item 4T. 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 March 31, 2009 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 director and our 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. On March 31, 2009 the U.S. District Court for the Southern District of New York dismissed the proceedings. On April 24, 2009 an appeal was filed with the United States Court of Appeals for the Second Circuit by the class action plaintiffs.

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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, 2008, as filed with the Securities and Exchange Commission on March 27, 2009.

Risks Related to Our Business

We may not be able to continue as a going concern. We will need substantial additional funds to continue operations, which we may not be able to raise on favorable terms, or at all.

We will need substantial additional funds in order to initiate any further preclinical studies or clinical trials, for debt obligations and to fund our operations through 2009. Our independent registered public accounting firm has included an explanatory paragraph in their report on our financial statements included in our Form 10-K for the year ended December 31, 2008 related to the uncertainty and substantial doubt of our ability to continue as a going concern. Our plan to address these matters is described in Note 1 to those financial statements. We believe that our cash and cash equivalents, which were approximately $6.3 million at March 31, 2009 will only fund our operations into the second quarter, and possibly the third quarter, of 2009. Although we intend to continue to seek additional financing or a strategic partner, we may not be able to complete a financing or corporate transaction, either on favorable terms or at all. If we are unable to complete a financing or strategic transaction, we do not expect to be able to continue as a going concern and may be required to file for bankruptcy, cease operations or liquidate and dissolve the Company.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in these risk factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. If we are able to obtain funds through arrangements with collaborative partners or others that require us to relinquish rights to technologies or product candidates that we would otherwise seek to develop or commercialize ourselves this may have a material adverse effect on our business, results of operations, financial condition or cash flow.

We are seeking to maximize the value of our assets, and address our liabilities and raise additional capital for our existing business. We are attempting to pursue asset out-licenses, asset sales, mergers or similar strategic transactions. We may be unable to satisfy our liabilities and can provide no assurances that we can be successful in executing a strategic transaction.

Due to our financial position, we are unable to initiate further preclinical studies or clinical trials. We are actively considering strategic alternatives with the goal of maximizing the value of our assets. In addition, we are considering our restructuring alternatives, including business arrangements such as the out-licensing or sale of product candidates or the Company as a whole. On April 15, 2009 we engaged Merriman Curhan Ford to assist in the evaluation of strategic options, including the possible sale of the company or its assets. There are substantial challenges and risks which will make it difficult to successfully implement any of these opportunities. Even if we determine to pursue one or more of these alternatives, we may be unable to do so on acceptable terms, if at all. In such event, we may be forced to file for bankruptcy, cease operations or liquidate and dissolve the Company.

Stockholders should recognize that in our efforts to address our liabilities and fund future operations and development of our product candidates, we may pursue strategic alternatives that result in the stockholders of the Company having little or no continuing interest in the assets of the Company as stockholders or otherwise. We will continue to evaluate our alternatives in light of our cash position, including the possibility that we may need to liquidate the Company.

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We may need to liquidate the Company in a voluntary dissolution under Delaware law or to seek protection under the provisions of the U.S. Bankruptcy Code, and in that event, it is unlikely that stockholders would receive any value for their shares.

We have incurred net operating losses every year since our inception. As of March 31, 2009, we had an accumulated deficit of approximately $121.3 million. As of April 30, 2009 we have been unable to raise the necessary capital to continue our existing operations. We are currently evaluating our strategic alternatives with respect to all aspects of our business. We cannot assure our stockholders that any actions that we take would raise or generate sufficient capital to fully address the uncertainties of our financial position. As a result, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business. If we are unable to settle our obligations to our creditors or if we are unable to consummate a strategic transaction we would likely need to liquidate the Company in a voluntary dissolution under Delaware law or to seek protection under the provisions of the U.S. Bankruptcy Code. In that event, we or a trustee appointed by the court may be required to liquidate our assets. In either of these events, we might realize significantly less value from our assets than their carrying values on our financial statements. The funds resulting from the liquidation of our assets would be used first to satisfy obligations to creditors before any funds would be available to our stockholders, and any shortfall in the proceeds would directly reduce the amounts available for distribution, if any, to our creditors and to our stockholders. In the event we were required to liquidate under Delaware law or the federal bankruptcy laws, it is highly unlikely that stockholders would receive any value for their shares.

We are currently not in compliance with Nasdaq rules regarding the minimum bid price and are at risk of being delisted from the Nasdaq Global Market, which may subject us to the SEC s penny stock rules and decrease the liquidity of our common stock.

We received a Nasdaq staff deficiency letter dated August 21, 2008 indicating that, for the prior 30 consecutive days, the bid price for the Company s common stock had closed below the minimum bid price of $1.00 per share as required for continued inclusion of the Nasdaq Global Market under Marketplace Rule 4450(a)(5). In accordance with Marketplace Rule 4450(e)(2), the Company has 180 calendar days to regain compliance with the minimum bid price requirement of $1.00 per share. In addition, as of March 25, 2009, the market value of our publicly held shares was less than $5 million, which is the minimum market value of publicly held shares required for continued listing under the Nasdaq Global Market s Marketplace Rules. However, Nasdaq has temporarily suspended, through July 20, 2009, the application of the continued listing requirements related to minimum bid price and minimum market value of publicly held shares for listing on the Nasdaq Global Market. Assuming the suspension is not extended, we will have until November 19, 2009, to regain compliance with the minimum bid price requirement of $1.00 per share. If the Company does not regain compliance by the end of such period, and does not elect or is unable to transfer to the Nasdaq Capital Market, Nasdaq will provide written notification that the Company s common stock will be delisted, after which the Company may appeal the staff determination to the Nasdaq Listing Qualifications Panel if it so chooses.

In addition, as of December 31, 2008 our stockholders equity was less than $10 million, which is the minimum required stockholders equity for continued listing on the Nasdaq Global Market. On March 31, 2009, we received written notice from Nasdaq of this lack of compliance with the continued listing criteria and further stated that we had until April 15, 2009 to provide Nasdaq with a specific plan to achieve and sustain compliance with the Nasdaq Capital Market listing requirements, including the time frame for completion of such plan. We provided such a plan to Nasdaq by this deadline, which, among other elements, included the potential sale of the Company or its assets. However, such events cannot be assured at the date of this report, and it is unknown whether Nasdaq will accept our plan to regain compliance with Nasdaq s continued listing criteria, or if we can successfully implement this plan.

If we are unable to regain compliance with the continued listing requirements, we expect that we would be delisted from the Nasdaq Global Market. Following any such delisting, our common stock may be traded over-the-counter on the OTC Bulletin Board or in the pink sheets. These alternative markets, however, are generally considered to be less efficient than, and not as broad as, the Nasdaq Global Market. Many OTC stocks trade less frequently and in smaller volumes than securities traded on the Nasdaq markets, which could have a material adverse effect on the liquidity of our common stock. If our common stock is delisted from the Nasdaq Global Market, there may be a limited market for our stock, trading in our stock may become more difficult and our share price could decrease even further. In addition, if our common stock is delisted, our ability to raise additional capital may be impaired.

Specifically, you may not be able to resell your shares of common stock at or above the price you paid for such shares or at all. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of management s attention and resources, which could hurt our business, operating results and financial condition.

In addition, our common stock may become subject to penny stock rules. The SEC generally defines penny stock as an equity security that has a market price of less than $5.00 per share, subject to certain exceptions. We are not currently subject to the penny stock rules because our common stock qualifies for an exception to the SEC s penny stock rules for companies that have an equity security that is quoted on the Nasdaq Stock Market. However, if we were delisted, our common stock would become subject to the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell our common stock. If our common stock were considered penny stock, the ability of

broker-dealers to sell our common stock and the ability of our stockholders to sell their shares in the secondary market would be limited and, as a result, the market liquidity for our common stock would be adversely affected. We cannot assure you that trading in our securities will not be subject to these or other regulations in the future.

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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 March 31, 2009 we had an accumulated deficit of approximately $121.3 million. If we are able to overcome our current financial issues and our operations were to continue, over the next several years we would expect a significant increase in our operating losses as we conduct additional 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 licensing agreements. Given the risks associated with 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 on-going 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. 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 two ionotropic glutamate receptor antagonists, tezampanel and NGX426, and muscarinic receptor agonist NGX267are clinical stage product candidates. NGX292 is a structurally similar backup compound to NGX267. 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 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 FDA or other regulatory agencies.

There is no certainty that the safety and efficacy results of our Phase IIb clinical trial for tezampanel in acute migraine announced in October 2007, our Phase I trial of NGX426 in a capsaicin induced pain model announced in December 2008 or our Phase II trial of NGX267 for the potential treatment of xerostomia announced in December 2008 are predictive of results in subsequent trials or are meaningful indicators of the safety and efficacy of the respective compounds. We will be required to perform additional clinical testing in order to obtain regulatory approval of our product candidates and the results of such additional clinical testing may not replicate what has been demonstrated to date regarding the safety and efficacy. Additionally, further testing 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;

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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.

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 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 development activities;

the prioritization and number of clinical development 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 our immediate funding needs or future additional funding needs will be available on acceptable terms, or at all. If the near term funds that we need to continue operations do not become available, we may be required to file for bankruptcy, cease operations or liquidate and dissolve the Company.

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 future clinical trials that will cause us or regulatory authorities to delay or suspend our clinical trials, or delay the analysis of data from such clinical trials. Any of the following factors could delay the clinical development of our product candidates:

- on-going 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;

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- 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.

Before we can demonstrate adequate safety and efficacy 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.

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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 ionotropic glutamate receptor antagonist assets tezampanel and 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 development and commercialization obligations. If Eli Lilly were to terminate the agreement, we would lose rights to the ionotropic glutamate receptor 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 receptor 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 development and commercialization obligations. If LSRI were to terminate the agreement, we would lose rights to the muscarinic receptor agonist product candidates, and our business would be adversely affected.

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

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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 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 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 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.

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Tezampanel and NGX426 belong to a new class of compounds. There are no compounds in this class 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 ionotropic glutamate receptor antagonists of the AMPA and kainite subtype. They are part of a new class of compounds that block the binding of glutamate to AMPA and kainite receptors and, in turn, stop the transmission of pain signals. Tezampanel and NGX426 may represent a novel approach to the treatment of numerous pain and non-pain diseases and disorders. There are currently no approved products that are ionotropic glutamate receptor antagonists of the AMPA and kainite subtype. As a result, we cannot be certain that tezampanel and NGX426 will result in commercially viable drugs.

NGX267 is being developed to treat xerostomia, or dry mouth. There are currently two muscarinic receptor agonists approved to treat xerostomia. We do not know if NGX267 will yield a commercially viable product or receive regulatory approval.

NGX267 is a muscarinic receptor agonist with functionally specific M1 receptor activity that we intend to develop for the treatment of xerostomia, or dry mouth. There are currently two muscarinic receptor agonists marketed in the United States for the treatment of xerostomia. We do not know whether or not NGX267 will have any advantages over the currently marketed products or will be safe and efficacious. Failure to demonstrate an advantage over the currently marketed products or a failure to be safe and efficacious will prevent us from commercializing NGX267 or generating significant revenue.

If our product candidates do not achieve market acceptance among physicians, patients, health care payers 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 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 team 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. On March 31, 2009 we reduced our work force to three employees. The three remaining employees, our Chief Executive Officer, Chief Financial Officer, and Vice President and General Counsel will assist the Board of Directors in assessing and completing any possible strategic transaction. In the event we receive funding for continued development of our product candidates 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.

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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. 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 on-going 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 which, if determined adversely, could have a material adverse affect on us.

A class action securities lawsuit was filed against us, as described under Part II, Item 1 Legal Proceedings. We are defending against this action vigorously; however, we do not know what the outcome of the 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 stock 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.

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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.

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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 on-going 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 on-going 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;

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suspend any on-going 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 in the areas in which we are competing, 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.

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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 are unable to successfully defend ourselves against any such 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 biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time-consuming and costly.

Our development processes involve the controlled use of hazardous materials, including chemicals 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 any future clinical trials of our product candidates;

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the results of planned 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.

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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.

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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 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 Registration Rights Agreement 1999 (incorporated by reference to Exhibit 4.4 to the Registrant s Annual Report on Form 10-KSB, filed on March 13, 2000).

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Number	Exhibits
4.4	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, filed on January 12, 2004).
4.5	Registration Rights Agreement dated as of May 3, 2004, between Axonyx Inc. and certain investors (incorporated by reference to Exhibit 4.2 to the Registrant s Current Report on Form 8-K, filed on May 5, 2004).
4.6	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).
4.7	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).
4.8	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).
4.9	Rights Agreement, dated as of May 13, 2005, between the Registrant and The 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).
4.10	Amendment to Rights Agreement, dated as of June 7, 2006, between the Registrant and The 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).
4.11	Amendment to Rights Agreement, dated as of October 3, 2006, between the Registrant and The 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).
4.12	Form of Warrant issued to Comerica Bank on June 11, 2008 (incorporated by reference to Exhibit 4.1 to the Registrant s Report on Form 8-K, filed on June 17, 2008).
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.

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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: May 1, 2009

TorreyPines Therapeutics, Inc.

By: /s/ Evelyn A. Graham

Evelyn A. Graham

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)