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.