NEUROCRINE BIOSCIENCES INC Form 10-Q May 06, 2009

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

FORM 10-Q

(Mark One)

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

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

For the transition period from ______ to _____

Commission file number 0-22705 NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of incorporation or organization)

33-0525145

(IRS Employer Identification No.)

12780 EL CAMINO REAL, SAN DIEGO, CALIFORNIA

92130

(Address of principal executive office)

(Zip Code)

(858) 617-7600

(Registrant s telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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 þ No o 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer b

Non-accelerated filer o

Smaller reporting company o

(Do not check if a smaller reporting company)

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

The number of outstanding shares of the registrant s common stock, par value \$0.001 per share, was 39,054,618 as of April 29, 2009.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEUROCRINE BIOSCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except for share information) (unaudited)

ASSETS	M	Iarch 31, 2009	D	31, 2008
Current assets:				
Cash and cash equivalents	\$	51,665	\$	68,467
Short-term investments, available-for-sale	Ψ	14,710	Ψ	12,006
Receivables under collaborative agreements		14,710		39
Other current assets		819		911
Other current assets		019		911
Total current assets		67,204		81,423
Property and equipment, net		5,075		6,191
Long-term investments		19,609		21,057
Restricted cash		6,404		6,409
Other non-current assets		2,736		3,102
Total assets	\$	101,028	\$	118,182
LIABILITIES AND STOCKHOLDERS EQUITY				
Current liabilities:				
Accounts payable	\$	2,551	\$	1,599
Accrued liabilities		9,056	·	10,905
Current portion of deferred revenues		2,922		2,936
Current portion of cease-use liability		15,202		7,870
Current portion of deferred gain on sale of real estate		2,805		2,784
TD 4.1 411.1111.11		22.526		26.004
Total current liabilities		32,536		26,094
Deferred revenues		10,946		11,676
Deferred gain on sale of real estate		32,151		32,867
Deferred rent		433		110
Cease-use liability		3,016		7,527
Other liabilities		2,835		3,134
Total liabilities		81,917		81,408
Commitments and contingencies				
Stockholders equity:				
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued				
and outstanding				
Common stock, \$0.001 par value; 110,000,000 shares authorized; issued and				
outstanding shares were 38,677,454 as of March 31, 2009 and 38,598,789 as of				
December 31, 2008		39		39
Additional paid-in capital		743,438		741,568

Accumulated other comprehensive loss Accumulated deficit	(1,438) (722,928)	(1,570) (703,263)
Total stockholders equity	19,111	36,774
Total liabilities and stockholders equity	\$ 101,028	\$ 118,182

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except loss per share data) (unaudited)

	Three Months Ended March 31,	
	2009	2008
Revenues:		
Sponsored research and development	\$ 17	\$ 12
License fees and milestones	730	1,730
Grant revenue		9
Total revenues	747	1,751
Operating expenses:		
Research and development	10,848	14,227
General and administrative	4,195	8,286
Cease-use expense	4,828	
Total operating expenses	19,871	22,513
Loss from operations	(19,124)	(20,762)
Other expense:		
Gain on sale/disposal of assets	141	34
Deferred gain on real estate	695	
Loss on auction rate securities	(1,448)	
Interest income	354	1,708
Interest expense		(1,921)
Other expense, net	(283)	(136)
Total other expense	(541)	(315)
Net loss	\$(19,665)	\$(21,077)
Net loss per common share:		
Basic and diluted	\$ (0.51)	\$ (0.55)
Shares used in the calculation of net loss per common share: Basic and diluted	38,669	38,330
Dasic and unuted	36,009	30,330

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands) (unaudited)

	Three Months Ended March 31,	
	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (19,665)	\$ (21,077)
Adjustments to reconcile net loss to net cash used in operating activities:		. () /
Depreciation and amortization	969	2,067
Gain on sale of assets	(141)	(34)
Fair value adjustment for auction rate security rights	211	,
Loss on sale of investments	320	
Fair value adjustment for auction rate securities	1,237	
Cease-use expense	4,828	
Deferred gain on sale of real estate	(695)	
Deferred revenues	(744)	(739)
Deferred rent	323	,
Share-based compensation expense	1,870	2,189
Amortization of premiums on short term-investments	(10)	(14)
Change in operating assets and liabilities:	,	,
Accounts receivable and other current assets	121	1,105
Other non-current assets	189	(139)
Accounts payable and accrued liabilities	(897)	(11,465)
Cease-use liability	(2,007)	, , ,
Other non-current liabilities	(299)	(74)
Net cash used in operating activities	(14,390)	(28,181)
CASH FLOWS FROM INVESTING ACTIVITIES	,	
Purchases of investments	(12,945)	(9,970)
Sales/maturities of investments	10,240	46,688
Deposits and restricted cash	5	6
Proceeds from sales of property and equipment	312	174
Purchases of property and equipment, net	(24)	(281)
Net cash (used in) provided by investing activities	(2,412)	36,617
CASH FLOWS FROM FINANCING ACTIVITIES	, ,	
Principal payments on debt		(461)
Net cash used in financing activities		(461)
Net (decrease) increase in cash and cash equivalents	(16,802)	7,975
Cash and cash equivalents at beginning of the period	68,467	99,664
Cash and cash equivalents at end of the period	\$ 51,665	\$ 107,639

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC. NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. BASIS OF PRESENTATION

The condensed consolidated financial statements included herein are unaudited. These statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, these financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of the financial position, results of operations, and cash flows for the periods presented. The results of operations for the interim period shown in this report are not necessarily indicative of results expected for the full year. These financial statements should be read in conjunction with the Management s Discussion and Analysis of Financial Condition and Results of Operations, Quantitative and Qualitative Disclosures About Market Risk and the financial statements and notes thereto for the year ended December 31, 2008 included in the Company s Annual Report on Form 10-K for the year ended December 31, 2008 filed with the SEC. Certain reclassifications have been made to previously reported amounts to conform to the current period presentation.

The terms Company and Neurocrine are used in this report to refer collectively to Neurocrine Biosciences, Inc. and its subsidiaries.

2. ORGANIZATION AND SUMMARY OF BUSINESS

Neurocrine Biosciences, Inc. discovers, develops and intends to commercialize drugs for the treatment of neurological and endocrine-related diseases and disorders. The Company s product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, anxiety, depression, pain, diabetes, benign prostatic hyperplasia, irritable bowel syndrome, and other neurological and endocrine-related diseases and disorders. The Company currently has eight programs in various stages of research and development, including five programs in clinical development. While the Company independently develops many of its own product candidates, Neurocrine is in collaborations with pharmaceutical companies for two of its programs. The Company s lead clinical development program, elagolix, is a drug candidate for the treatment of endometriosis.

3. IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS

In April 2009, the Financial Accounting Standards Board (FASB) issued several pronouncements related to fair value measurement, recording and disclosure in financial reporting.

FASB Staff Position No. 107-1 and Accounting Principles Board (APB) 28-1, Interim Disclosures about Fair Value of Financial Instruments, were issued to outline the required financial statement disclosures relating to fair value of financial instruments during interim reporting periods. FASB Staff Position No. 157-4, Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly, was issued to provide additional guidance in evaluating the fair value of a financial instrument when the volume and level of activity for the asset or liability has significantly decreased. FASB Staff Position No. 115-2 and FASB Staff Position No. 124-2, Recognition and Presentation of Other-Than-Temporary Impairments, were issued to provide additional guidance on presenting impairment losses on securities.

All of the above mentioned pronouncements will be effective for interim and annual reporting periods ending after June 15, 2009, and early adoption is permitted. The Company does not expect the adoption of these new pronouncements to have a material effect on its consolidated results of operations or financial condition.

In May 2008, the FASB issued Statement of Financial Accounting Standards (SFAS) 162, The Hierarchy of Generally Accepted Accounting Principles (SFAS 162). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statement of nongovernmental entities that are presented in conformity with generally accepted accounting principles. SFAS 162 will become effective 60 days following the SEC s approval of the Public Company Accounting

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Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. The Company does not expect the adoption of SFAS 162 to have a material effect on its consolidated results of operations or financial condition.

In December 2007, the FASB issued SFAS 141 (revised 2007), Business Combinations (SFAS 141(R)). SFAS 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired in connection with business combinations. SFAS 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141(R) is effective for fiscal years beginning on or after December 15, 2008. The adoption of SFAS 141(R) did not have a material effect on the Company s consolidated results of operations or financial condition.

In December 2007, the FASB issued SFAS 160, Noncontrolling Interests in Consolidated Financial Statements an amendment of Accounting Research Bulletin No. 51 (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent s ownership interest, and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for fiscal years beginning after December 15, 2008. The adoption of SFAS 160 did not have a material effect on the Company s consolidated results of operations and financial condition.

In March 2008, the FASB issued SFAS 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133 (SFAS 161). SFAS 161 applies to all derivative instruments and related hedged items accounted for under SFAS 133, Accounting for Derivative Instruments and Hedging Activities (SFAS 133). SFAS 161 requires entities to provide greater transparency about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations, and how derivative instruments and related hedged items affect an entity s financial position, results of operations and cash flows. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The adoption of SFAS 161 did not have a material effect on the Company s consolidated results of operations and financial condition.

4. USE OF ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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.

5. SHORT-TERM INVESTMENTS AVAILABLE FOR SALE

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

6. LONG-TERM INVESTMENTS

The Company s long-term investments at March 31, 2009 included (at par value) \$22.6 million of auction rate securities, \$14.6 million of which are maintained by UBS AG (UBS) and \$8.0 million of which are maintained by Citigroup (Citi). With the liquidity issues experienced in global credit and capital markets, these auction rate securities have experienced multiple failed auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders, and as a result, these affected securities are currently not liquid. However, the Company now earns a higher interest rate according to the terms of these securities. All of the Company s auction rate securities are secured by student loans, which are backed by the full faith and credit of the federal government (up to approximately 98% of the value of the student loan). All of these securities continue to pay interest according to their stated terms (generally 120 basis points over the ninety-one day United States Treasury bill rate) with interest rates resetting every 7 to

28 days. While it is not the Company s intent to hold these securities until their stated ultimate maturity dates, these investments are scheduled to ultimately mature between 2030 and 2047.

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The valuation of the Company s auction rate securities investment portfolio is subject to uncertainties that are difficult to predict. The fair values of these securities are estimated utilizing a discounted cash flow analysis as of March 31, 2009. The significant assumptions of this valuation model were discount margins ranging from 254 to 931 basis points which are based on industry recognized student loan sector indices, an additional required rate of return of 150 basis points and an estimated term to liquidity of 6 to 8 years. Other items this analysis considers are the collateralization underlying the security investments, the creditworthiness of the counterparty, and the timing of expected future cash flows. These securities were also compared, when possible, to other observable market data with similar characteristics as the securities held by the Company. Although the auction rate security investments continue to pay interest according to their stated terms, based on valuation models of the individual securities, the Company has recognized in the consolidated statement of operations for the three months ending March 31, 2009 a loss of approximately \$1.5 million on auction rate securities in other expense for which for the Company has concluded that an other-than-temporary impairment exists. The carrying value in long-term investments for these auction rate securities at March 31, 2009 is \$17.5 million.

During the fourth quarter of 2008, UBS extended an offer of Auction Rate Securities Rights (ARS Rights) to holders of illiquid auction rate securities that were maintained by UBS as of February 13, 2008. The ARS Rights provide the holder with the ability to sell the auction rate securities, along with the ARS Rights, to UBS at the par value of the auction rate securities, during an applicable exercise period. The ARS Rights grant UBS the sole discretion and right to sell or otherwise dispose of auction rate securities at any time up until July 2, 2012, without any prior notification of the holder, so long as the holder receives a payment of par upon any sale or disposition. The ARS Rights are not transferable, not tradeable, and will not be quoted or listed on any securities exchange or any other trading network. The offer period for the ARS Rights closed on November 14, 2008 and ARS Rights were issued by UBS during the fourth quarter of 2008.

The Company elected to participate in the ARS Rights program for all of its outstanding auction rate securities maintained by UBS. The Company has \$14.6 million (at par value) of auction rate securities that are maintained by UBS. Under the terms of the ARS Rights offer, the applicable exercise period begins on June 30, 2010 and ends July 2, 2012. Additionally, the Company is eligible for a loan of up to 75% of the market value of the auction rate securities, should a loan be needed. It is the Company s intention to sell the auction rate securities and ARS Rights to UBS on June 30, 2010.

The Company has elected to measure the ARS Rights under the fair value option of SFAS 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment to FASB Statement No. 115 (SFAS 159) to mitigate volatility in reported earnings due to their linkage to the auction rate securities. The ARS Rights were valued in a similar fashion to the auction rate securities as described above. Simultaneously, due to the ARS Rights granted by UBS, the Company made a one-time election to transfer the related auction rate security holdings from available-for-sale securities to trading securities. The Company anticipates that any changes in the fair value of the ARS Rights will be offset by the changes in the fair value of the related auction rate securities with no material net impact to the consolidated statement of operations. The ARS Rights will continue to be measured at fair value under SFAS 159 until the earlier of their maturity or exercise. At March 31, 2009, the Company valued these ARS Rights at \$2.1 million.

The Company s remaining auction rate securities that are maintained by Citi continue to be treated as available-for-sale investments. These auction rate securities have a par value of \$8.0 million. During the first quarter of 2009, certain ratings agencies downgraded these auction rate securities and the Company recognized an other-than-temporary impairment of \$1.5 million in the consolidated statement of operations for the three months ended March 31, 2009. At March 31, 2009, the Company valued these investments at \$5.3 million.

At present, in the event the Company needs to access the funds that are in an illiquid state, the Company may not be able to do so without the possible loss of principal until a future auction for these investments is successful, another secondary market evolves for these securities, they are redeemed by the issuer or they mature. If the Company is unable to sell these securities in the market or they are not redeemed, the Company could be required to hold them to maturity.

Changes to estimates and assumptions used in estimating the fair value of the auction rate securities and related ARS Rights may provide materially different values. In addition, actual market exchanges, if any, may occur at materially different amounts. For example, a reduction of the expected term to redemption assumption by approximately two years for the auction rate securities and related ARS Rights would yield a net increase in the valuation of these investments of \$0.5 million. Other factors that may impact the valuation of the Company s auction rate securities and related ARS Rights include changes to credit ratings of the securities as well as

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to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity.

7. FAIR VALUE MEASUREMENTS

The Company adopted SFAS 157, Fair Value Measurements (SFAS 157) on January 1, 2008. SFAS 157, among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. SFAS 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets measured at fair value as of March 31, 2009 are classified below based on the three fair value hierarchy tiers described above (in millions):

		Fair Value M Quoted Prices in Active Markets for Identical	easurements at Ma Significant Other Observable	orch 31, 2009 Using Significant Unobservable
		Assets	Inputs	Inputs
	March			
Description	31, 2009	(Level 1)	(Level 2)	(Level 3)
Cash and money market funds	\$58.0	\$ 58.0	\$	\$
Certificates of Deposit ⁽¹⁾	12.7	12.7		
Corporate debt securities ⁽¹⁾	2.0	2.0		
Auction rate securities ⁽²⁾	17.5			17.5
ARS Rights (Note 6)	2.1			2.1
Total	\$92.3	\$ 72.7	\$	\$ 19.6

Activity for assets measured at fair value during the three month period ended March 31, 2009 using significant unobservable inputs

(Level 3) is presented in the table below (in millions):

Fair Value
Measurements Using
Significant
Unobservable
Inputs
(Level 3)
\$ 21.1

Beginning balance as of December 31, 2008

Transfers into Level 3

Purchases, sales, issuances, and settlements (net)

Total unrealized losses included in other comprehensive income Total unrealized losses included in other expense

(1.5)

Ending balance \$ 19.6

- (1) Securities are classified as available-for-sale.
- (2) The Company transferred a portion of its action rate securities from available-for-sale to trading in the fourth quarter of 2008. The fair value of these auction rate securities was estimated based on the following: (i) the underlying structure of each security; (ii) the present value of future principal and interest payments discounted at rates considered to reflect current market conditions; (iii) consideration of the probabilities of default, auction failure, or repurchase at par for each period;

(iv) the expected term to liquidity; and (v) its market required rate of

return.

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8. IMPAIRMENT OF LONG-LIVED ASSETS

In accordance with SFAS 144, Accounting for the Impairment or Disposal of Long-Lived Assets, if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If the carrying amount is not recoverable, the Company measures the amount of any impairment by comparing the carrying value of the asset to the present value of the expected future cash flows associated with the use of the asset. The Company has determined that no impairment exists on its long-lived assets.

9. SHARE-BASED COMPENSATION

The Company s net loss for the three months ended March 31, 2009 and 2008 included \$1.9 million and \$2.2 million, respectively, of compensation expense related to the Company s share-based compensation awards. As of March 31, 2009, total unrecognized estimated compensation cost related to non-vested stock options and non-vested restricted stock units (RSUs) granted prior to that date was \$2.2 million and \$5.1 million, respectively, which is expected to be recognized over a weighted average period of approximately 1.2 and 1.5 years, respectively. The compensation expense related to the Company s share-based compensation arrangements is recorded as components of general and administrative expense and research and development expense. The following is a summary of the components of the Company s compensation expense related to share-based compensation (in millions):

	Three	Months
	En	ded
	March 31,	
	2009	2008
General and administrative	\$ 0.9	\$ 1.3
Research and development	1.0	0.9

There were no stock option exercises for the three months ended March 31, 2009 or 2008. The Company issued approximately 0.3 million shares of common stock pursuant to the vesting of RSUs during the three months ended March 31, 2009.

Stock Option Assumptions

There were no stock option grants during the three months ended March 31, 2009. The exercise price of all options granted during the three month period ended March 31, 2008 was equal to the closing price of the Company s common stock on the date of grant. For grants of stock options prior to January 1, 2009, the estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option valuation model. The following weighted-average assumptions were used for option grants during the three months ended March 31, 2008:

	Three
	Months
	Ended
	March 31,
	2008
Risk-free interest rate	2.49%
Expected volatility of common stock	68.74%
Dividend yield	0.0%
Expected option term	4.75 years

The Company estimates forfeiture rates for options based on past behavior for similar options with further consideration given to the class of employees to whom the options were granted.

10. RESTRUCTURING CHARGES

In December 2007, the Company announced a restructuring program to implement cost containment measures and to focus research and development efforts. As a result, the Company reduced its research and development and general and administrative staff in San Diego by approximately 125 employees. Restructuring charges are comprised of salary continuation, outplacement services, and other miscellaneous costs related to this reduction in force.

Substantially all of these expenses were paid in cash during the first quarter of 2008. During the first quarter of 2008, the Company recorded an additional net charge of \$2.1 million (primarily all general and administrative expense) for severance related to certain executives and other personnel departing the Company.

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As of March 31, 2009, the Company had a remaining balance of approximately \$1.1 million of accrued restructuring expenses included in the Condensed Consolidated Balance Sheet. This liability will be paid over the remaining contractual period of certain severance agreements. The changes to the accrued liability for the first three months of 2009 are as follows (in thousands):

Accrual balance as of December 31, 2008	\$ 1,578
Payments	(497)
Adjustments	(8)
Accrual balance as of March 31, 2009	\$ 1,073

11. REAL ESTATE

Effective December 10, 2008, the Company entered into a First Amendment to Lease (Lease Amendment) with DMH Campus Investors, LLC (DMH). The Company and DMH are parties to a lease agreement, dated December 4, 2007, pursuant to which the Company leases its corporate headquarters, located at 12790 El Camino Real (Front Building) and 12780 El Camino Real (Rear Building) in San Diego, California (Lease). The Lease Amendment provides for the renovation of the Front Building in a manner that facilitates multiple tenant usage and establishes a mechanism for the Company to terminate its use of the Front Building. The Company will continue to occupy the Rear Building.

During the fourth quarter of 2008, the Company vacated the Front Building. In accordance with SFAS 146, Accounting for Costs Associated with Exit or Disposal Activities (SFAS 146), a liability of \$15.7 million was recorded for estimated lease termination costs. Estimated lease termination costs include future minimum lease payments, taxes, insurance, construction, and maintenance costs from the cease-use date to the end of the remaining lease term net of estimated sublease rental income. During the first quarter of 2009, the Company adjusted the liability in response to the declining economic conditions in San Diego, by extending the expected period to lease the Front Building. In addition, certain other period costs such as leasing commissions and legal fees will be borne by the Company in the event of the sublease of the Front Building. If estimated net sublease rental income were to change by 10% in either direction, the Company is estimated lease termination costs would increase or decrease by approximately \$1.7 million.

(Amounts in millions)	Quarter Ended March 31, 2009	
Accrued lease termination costs at beginning of period Lease termination costs accrued during the	\$	15.4
period		0.3
Changes in assumptions about future sublease income		4.5
Cash payments for lease termination costs		(2.0)
Accrued lease termination costs at end of period Less current portion of accrued lease	\$	18.2
termination costs		15.2
Non-current portion of accrued lease termination costs	\$	3.0

In accordance with SFAS 98, Accounting for Leases: Sale-Leaseback Transactions Involving Real Estate, Sales-Type Leases of Real Estate, Definition of the Lease Term, and Initial Direct Costs of Direct Financing Leases (SFAS 98) and SFAS 66, Accounting for Sales of Real Estate (SFAS 66) the Company initially deferred the gain on the sale of the building and related vacant parcel due to a repurchase right. The Company initially established a long-term liability of \$108.7 million upon the close of the transaction, essentially the gross proceeds from the real estate sale. The lease amendment terminated this repurchase right and the Company removed from its balance sheet the long-term liability of \$108.7 million and the related previously conveyed real estate related assets of \$69.6 million during the fourth quarter of 2008. Additionally, the Company began to recognize the deferred gain of \$39.1 million on the sale of the real estate in accordance with SFAS 66 and SFAS 98. During the first quarter of 2009, the Company recognized \$0.7 million of the deferred gain and will recognize the balance of the deferred gain over the remaining lease term.

12. LOSS PER COMMON SHARE

The Company computes net loss per share in accordance with SFAS No. 128, Earnings Per Share (SFAS 128). Under the provisions of SFAS 128, basic net loss per share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the

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weighted average number of common and common equivalent shares outstanding during the period. Additionally, potentially dilutive securities, composed of incremental common shares issuable upon the exercise of stock options and warrants, are excluded from historical diluted loss per share because of their anti-dilutive effect. Potentially dilutive securities totaled 0.2 million and 0.1 million for the three months ended March 31, 2009 and 2008, respectively.

13. COMPREHENSIVE LOSS

Comprehensive loss is calculated in accordance with SFAS 130, Comprehensive Income (SFAS 130). SFAS 130 requires the disclosure of all components of comprehensive loss, including net loss and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. The Company s components of comprehensive loss consist of the net loss and unrealized gains and losses on available-for-sale investments. For the three months ended March 31, 2009 and 2008, comprehensive loss was \$19.5 million and \$22.2 million, respectively.

14. REVENUE RECOGNITION

Revenues under collaborative research agreements and grants are recognized as research costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis, do not require scientific achievement as a performance obligation and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. Upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned are classified as deferred revenue and recognized as income over the contract or development period. Estimating the duration of the development period includes continual assessment of development stages and regulatory requirements. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events, which require substantive effort, and for which achievement of the milestone was not readily assured at the inception of the agreement.

15. RESEARCH AND DEVELOPMENT

Research and development (R&D) expenses are recognized as incurred and include related salaries, contractor fees, clinical trial costs, facilities costs, administrative expenses and allocations of certain other costs. These expenses result from the Company s independent R&D efforts as well as efforts associated with collaborations and in-licensing arrangements. In addition, the Company funds R&D at other companies and research institutions under agreements, which are generally cancelable. The Company reviews and accrues clinical trial expenses based on work performed, a method that relies on estimates of total costs incurred based on patient enrollment, completion of patient studies and other events. The Company follows this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

16. INCOME TAXES

On July 13, 2006, the FASB issued FASB Interpretation No. 48 (FIN 48), Accounting for Uncertainty in Income Taxes, an interpretation of FASB No. 109. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company adopted the provisions of FIN 48 on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption. As a result of the implementation of FIN 48, the Company did not recognize an increase in the liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company s practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company s balance sheets at December 31, 2008 and at March 31, 2009, and has not recognized interest and/or penalties in the statement of operations for the first three months of 2009.

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The Company is subject to taxation in the United States and various state jurisdictions. The Company s tax years for 1993 and forward are subject to examination by the United States and California tax authorities due to the carryforward of unutilized net operating losses and R&D credits.

At January 1, 2009, the Company had net deferred tax assets of \$69.3 million. Due to uncertainties surrounding the Company s ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the net deferred tax assets. Additionally, the future utilization of the Company s net operating loss and research and development credit carryforwards to offset future taxable income may be subject to a substantial annual limitation, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that may have occurred previously or that could occur in the future. Although the Company determined that an ownership change had not occurred through January 31, 2007, it is possible that an ownership change occurred subsequent to that date. The Company has not completed an update of its Section 382 analysis subsequent to January 31, 2007. Until this analysis has been updated, the Company has removed the deferred tax assets for net operating losses of \$227.2 million and research and development credits of \$38.8 million generated through 2008 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. Due to the existence of the valuation allowance, future changes in the Company s unrecognized tax benefits will not impact the Company s effective tax rate.

In May 2009, the Company announced staff reductions of approximately 60 employees as part of its restructuring program to prioritize its clinical development programs. As a result, during the second quarter of 2009 the Company communicated to affected employees a plan of organizational restructuring through involuntary terminations. Pursuant to SFAS 112, Employers Accounting for Post-employment Benefits and SFAS 146, the Company expects to incur a severance charge of approximately \$3.0 million in the second quarter of 2009. The majority of this amount is expected to be paid out during the second quarter of 2009. Additionally, the Company elected to suspend any matching contributions to the Company 401(k) program and to terminate its deferred compensation plan during the second quarter of 2009. The related assets of the deferred compensation plan, carried as other non-current assets on the Condensed Consolidated Balance Sheet, will be distributed to participants in accordance with plan provisions. Additionally, the liabilities of the deferred compensation plan, carried as other liabilities in the Condensed Consolidated Balance Sheet, will be relieved as the plan assets are distributed.

ITEM 2: MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management s Discussion and Analysis of Financial Condition and Results of Operations section contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A under the caption Risk Factors. The interim financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the Financial Statements and Notes thereto for the year ended December 31, 2008 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2008.

OVERVIEW

We discover, develop and intend to commercialize drugs for the treatment of neurological and endocrine-related diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia, and other neurological and endocrine related diseases and disorders. To date, we have not generated any revenues from the sale of products. We have funded our operations primarily through private and public offerings of our common stock and payments received under research and development agreements. We are developing certain products with corporate collaborators and intend to rely on existing and future collaborators to meet funding requirements. We expect to generate future net losses due to increases in operating expenses as product candidates are advanced through the various stages of clinical development. As of March 31, 2009, we had an accumulated deficit of \$722.9 million and expect to incur operating losses in the near future, which may be greater than losses in prior years. We currently have eight programs in various stages of research and development, including five programs in clinical development. While

we independently develop many of our product candidates, we are in a collaboration for two of our programs. CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to revenues under collaborative

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research agreements and grants, clinical trial accruals (research and development expense), debt, share-based compensation, investments, and fixed assets. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the 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. The items in our financial statements requiring significant estimates and judgments are as follows:

Revenues under collaborative research and development agreements are recognized as costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis, do not require scientific achievement as a performance obligation, and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. Upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned are classified as deferred revenue and recognized as income over the contract or development period. Estimating the duration of the development period includes continual assessment of development stages and regulatory requirements. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events, which requires substantive effort, and for which achievement of the milestone was not readily assured at the inception of the agreement.

Research and development (R&D) expenses include related salaries, contractor fees, facilities costs, administrative expenses and allocations of corporate costs. All such costs are charged to R&D expense as incurred. These expenses result from our independent R&D efforts as well as efforts associated with collaborations, grants and in-licensing arrangements. In addition, we fund R&D and clinical trials at other companies and research institutions under agreements, which are generally cancelable. We review and accrue clinical trials expense based on work performed, a method that relies on estimates of total costs incurred based on patient enrollment, completion of studies and other events. We follow this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to R&D costs; however a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144 (SFAS 144), Accounting for the Impairment or Disposal of Long-Lived Assets, if indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the estimated fair value of the asset, which is generally determined based on the present value of the expected future cash flows. We have determined that no impairment exists on our long-lived assets.

We grant stock options to purchase our common stock to our employees and directors under the 2003 Incentive Stock Plan, as amended (the 2003 Plan) and grant stock options to certain employees pursuant to Employment Commencement Nonstatutory Stock Option Agreements. We also grant certain employees stock bonuses and RSUs under the 2003 Plan. Additionally, we have outstanding options that were granted under option plans from which we no longer make grants. The benefits provided under all of these plans are subject to the provisions of revised SFAS No. 123, Share-Based Payment (SFAS 123R). Share-based compensation expense recognized under SFAS 123R for the three months ended March 31, 2009 and 2008 was \$1.9 million and \$2.2 million, respectively.

Stock option awards and RSUs generally vest over a three to four year period and expense is ratably recognized over those same time periods. However, due to certain retirement provisions in our stock plans, share-based compensation expense may be recognized over a shorter period of time, and in some cases the entire share-based compensation expense may be recognized upon grant of the share-based compensation award. Employees who are age 55 or older and have five or more years of service with us are entitled to accelerated vesting of certain unvested share-based compensation awards upon retirement. This retirement provision leads to variability in the quarterly expense amounts recognized under SFAS 123R, and therefore individual share-based compensation awards may impact earnings disproportionately in any individual fiscal quarter.

The determination of fair value of stock-based payment awards on the date of grant using the Black-Scholes model is affected by our stock price, as well as the input of other subjective assumptions. These assumptions include, but are not limited to, the expected

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term of stock options and our expected stock price volatility over the term of the awards. Our stock options have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates.

SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. If actual forfeitures vary from our estimates, we will recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

THREE MONTHS ENDED MARCH 31, 2009 AND 2008

Revenues were \$0.7 million for the first quarter of 2009 compared with \$1.8 million for the respective period last year. The decrease in revenues for the three months ended March 31, 2009, compared with the respective period in 2008, is primarily from revenues recognized in 2008 under our collaboration agreement with GlaxoSmithKline (GSK). During the first quarter of 2008, we recognized \$1.0 million in milestone revenue from GSK. Additionally, during the first quarters of both of 2009 and 2008, we recognized \$0.7 million in revenue under our collaboration agreement with Dainippon Sumitomo Pharma Co. Ltd (DSP) from amortization of up-front licensing fees. &nb