NEUROCRINE BIOSCIENCES INC
Form 10-Q
May 06, 2009

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

FORM 10-Q

(Mark One)

þ **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	**33-0525145**
(State or other jurisdiction of incorporation or organization)	(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 þ 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 þ

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)

	March 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,665	$ 68,467
Short-term investments, available-for-sale	14,710	12,006
Receivables under collaborative agreements	10	39
Other current assets	819	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
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	(1,438)	(1,570)
Accumulated deficit	(722,928)	(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

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 Measurements at March 31, 2009 Using		
Description	**March 31, 2009**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (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)
Beginning balance as of December 31, 2008	$ 21.1
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 Ended 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 s 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	$ 15.4
Lease termination costs accrued during the 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	$ 18.2
Less current portion of accrued lease 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.

17. SUBSEQUENT EVENTS

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.

Research and development expenses decreased to $10.8 million for the first quarter of 2009 compared with $14.2 million for the respective period in 2008. Laboratory costs decreased by $0.3 million in the first quarter of 2009 compared to the same period in 2008 and external development costs decreased by $2.1 million compared to last year. External development spending in our elagolix program decreased from $3.7 million in the first quarter of 2008 to $1.9 million in the first quarter of 2009. In addition, depreciation expense decreased by $0.8 million in the first quarter of 2009 compared with the same period last year as a result of the termination of our right to repurchase any portion of our facility or real property in the fourth quarter of 2008.

General and administrative expenses were $4.2 million for the first quarter of 2009 compared with $8.3 million during the same period last year. This decrease in general and administrative expenses is primarily due to severance costs and additional stock option compensation expense for accelerated vesting of certain stock grants of $2.4 million incurred in the first quarter of 2008.

During the first quarter of 2009, we recognized additional cease-use expense under SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities (SFAS 146) of $4.8 million due to an estimated increase in construction costs, and a change in assumptions on the timing of tenant occupancy and rental rates for the Front Building. See Note 11, Real Estate to the accompanying Financial Statements.

Other expense increased from $0.3 million during the first quarter of 2008 to $0.5 million for the first quarter of 2009. The increase resulted primarily from rental payments made during the first quarter of 2008 under our sale-leaseback agreement which were previously recorded as interest expense under sale-leaseback accounting rules. These rental payments are components of operating expenses during 2009. Additionally, investment income for the first quarter of 2009 decreased by $1.4 million from the prior year period, primarily due to lower cash balances coupled with lower overall interest rates, as well as a $1.5 million recognized loss on an other-than-temporary impairment of our auction rate securities and a $0.3 million realized loss on deferred compensation investments.

Net loss for the first quarter of 2009 was $19.7 million, or $0.51 per share, compared to $21.1 million, or $0.55 per share, for the same period in 2008. This decrease in net loss was primarily due to severance costs incurred in the first quarter of 2008 and expense management efforts during the first quarter of 2009.

In May 2009, we announced staff reductions of approximately 60 employees as part of our restructuring program to prioritize our clinical development programs. As a result, during the second quarter of 2009 we 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, we expect 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, we elected to suspend any matching contributions to the 401(k) program and to terminate our deferred compensation plan during the second quarter of 2009. The related assets of the deferred compensation plan, carried as other non-current assets on our balance sheet will be distributed to participants in accordance with the provisions of the plan. Additionally, the liabilities of the deferred compensation plan, carried as other liabilities in our balance sheet will be relieved as the assets are distributed.

To date, our revenues have been derived primarily from funded research and development, achievements of milestones under corporate collaborations, and licensing of product candidates. The nature and amount of these revenues from period to period may lead to substantial fluctuations in our of quarterly revenues and earnings. Accordingly, results and earnings for one period are not predictive of future periods. Collaborations, including grant revenue, accounted for 100% of our revenue for the three months ended March 31, 2009 and 2008.

We expect to incur operating losses for the foreseeable future because of the expenses we expect to incur related to progressing programs through our pipeline.

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LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2009, our cash, cash equivalents, and investments totaled $86.0 million compared with $101.5 million at December 31, 2008. The decrease in cash and investment balances at March 31, 2009 resulted primarily from our net loss of $19.7 million, which includes various non-cash expenditures.

Our long-term investments at March 31, 2009 included (at par value) $22.6 million of auction rate securities. 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. All of our 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 our intent to hold these securities until their stated ultimate maturity dates, these investments are scheduled to ultimately mature between 2030 and 2047.

The valuation of our auction rate securities investment portfolio is subject to uncertainties that are difficult to predict. The fair values of these securities were 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 liquidity discount 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 us. Although the auction rate security investments continue to pay interest according to their stated terms, based on valuation models of the individual securities, we have recognized in the consolidated statement of operations for the three months ended March 31, 2009 a loss of approximately $1.5 million in other expense, net for auction rate securities that we have concluded that an other-than-temporary impairment exists. The carrying value in long-term investments for these auction rate securities at March 31, 2009 was $17.5 million.

During the fourth quarter of 2008, UBS AG (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.

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

We 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 of FASB Statement No. 115 (SFAS 159), to mitigate volatility in reported earnings due to their linkage to the auction rate securities. Simultaneously, due to the ARS Rights granted by UBS, we made a one-time election to transfer the related auction rate security holdings from available-for-sale securities to trading securities. We anticipate 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, we valued these ARS Rights at $2.1 million.

Our remaining auction rate securities that are not maintained by UBS 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 we 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, we valued these investments at $5.3 million.

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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 our auction rate securities and related ARS Rights include changes to credit ratings of the securities as well as 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.

At present, in the event we need to access the funds that are in an illiquid state, we 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 we are unable to sell these securities in the market or they are not redeemed, we could be required to hold them to maturity. We do not currently anticipate a need to access these funds for operational purposes in 2009, nor the outstanding auction rate securities with UBS prior to June 30, 2010, the beginning of the ARS Rights exercise period. We will continue to monitor and evaluate these investments on an ongoing basis for impairment.

Net cash used in operating activities during the first three months of 2009 was $14.4 million compared with $28.2 million during the same period last year. Net loss for the first three months of 2009 was $19.7 million compared to $21.1 million for the same period in 2008. This decrease in net loss was primarily due to severance costs incurred in the first quarter of 2008 and expense management efforts during the first quarter of 2009.

Net cash used in investing activities during the first three months of 2009 was $2.4 million compared to net cash provided by investing activities of $36.6 million for the first three months of 2008. The fluctuation in net cash provided by investing activities resulted primarily from the timing differences in investment purchases, sales and maturities, and the fluctuation of our portfolio mix between cash equivalents and short-term investment holdings.

No cash was utilized in financing activities during the first three months of 2009 compared to $0.5 million used in 2008 related to cash payments made on outstanding debt obligations.

The terms of our facility lease agreement require that we maintain $50.0 million in cash and investments at all times, or increase our security deposit by $5.0 million.

We believe that our existing capital resources, together with interest income and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, we cannot guarantee that these capital resources and payments will be sufficient to conduct all of our research and development programs as planned. The amount and timing of expenditures will vary depending upon a number of factors, including progress of our research and development programs.

We will require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, the cost of product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. In addition, we have financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. However, additional equity or debt financing might not be available on reasonable terms, if at all, and any additional equity financings will be dilutive to our stockholders. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. If adequate funds are not available, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or product candidates. To the extent that we are unable to obtain third-party funding for such expenses, we expect that increased expenses will result in increased losses from operations.

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We cannot assure you that we will be successful in the development of our product candidates, or that, if successful, any products marketed will generate sufficient revenues to enable us to earn a profit.

INTEREST RATE RISK

We are exposed to interest rate risk on our short and long term investments. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest in short-term securities and ensure that the maximum initial average maturity of our investments does not exceed 36 months. If a 10% change in interest rates had occurred on March 31, 2009, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to the short holding period of our investments and the nature of our investments, we have concluded that we do not have a material financial market interest rate risk exposure.

NEW ACCOUNTING PRONONCEMENTS

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. We do not expect the adoption of these new pronouncements to have a material effect on our consolidated results of operations or financial condition.

In May 2008, the FASB issued 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 Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. We do not expect the adoption of SFAS 162 to have a material effect on our 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 our consolidated results of operations and 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 our consolidated results of operations and financial condition.

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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 our consolidated results of operations and financial condition.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, plan, intends, estimates, could, should, would, continue, seeks, proforma, similar words (including their use in the negative), or by discussions of future matters such as the development or regulatory approval of new products, technology enhancements, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions Risk Factors, and Management s Discussion and Analysis of Financial Condition and Results of Operations as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading in Part II titled Item 1A. Risk Factors and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

A discussion of our exposure to, and management of, market risk appears in Part I, Item 2 of this Quarterly Report on Form 10-Q under the heading Interest Rate Risk.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II: OTHER INFORMATION

ITEM 1A. RISK FACTORS

The following Risk Factors do not reflect any material changes to the Risk Factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008, other than the revisions to the risk factors set forth below with an asterisk (*) next to the title. The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations.

Risks Related to Our Company

We depend on continuing our current collaborations and developing additional collaborations to develop and commercialize our product candidates.

Our strategy for fully developing and commercializing our products is dependent upon maintaining our current arrangements and establishing new arrangements with research collaborators, corporate collaborators and others, particularly as it relates to our GnRH and urocortin 2 programs. We have active collaboration agreements with GlaxoSmithKline and Dainippon Sumitomo Pharma Co. Ltd. and previously have had collaborations with Pfizer, Wyeth, Johnson & Johnson, Novartis, Taisho and Eli Lilly and Company. We historically have been dependent upon these corporate collaborators to provide adequate funding for a number of our programs. Under these arrangements, our corporate collaborators are typically responsible for:

selecting compounds for subsequent development as drug candidates;

conducting preclinical studies and clinical trials and obtaining required regulatory approvals for these drug candidates; and

manufacturing and commercializing any resulting drugs.

Because we expect to continue to rely heavily on corporate collaborators, the development and commercialization of our programs would be substantially delayed if one or more of our current or future collaborators:

failed to select a compound that we have discovered for subsequent development into marketable products;

failed to gain the requisite regulatory approvals of these products;

did not successfully commercialize products that we originate;

did not conduct its collaborative activities in a timely manner;

did not devote sufficient time and resources to our partnered programs or potential products;

terminated its alliance with us;

developed, either alone or with others, products that may compete with our products;

disputed our respective allocations of rights to any products or technology developed during our collaborations; or

merged with a third party that wants to terminate the collaboration.

These issues and possible disagreements with current or future corporate collaborators could lead to delays in the collaborative

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research, development or commercialization of many of our product candidates. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and expensive. If any of these issues arise, it may delay the development and commercialization of drug candidates and, ultimately, our generation of product revenues.

Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.

Before obtaining regulatory approval for the sale of any of our potential products, we must subject these product candidates to extensive preclinical and clinical testing to demonstrate their safety and efficacy for humans. Clinical trials are expensive, time-consuming and may take years to complete.

In connection with the clinical trials of our product candidates, we face the risks that:

the product candidate may not prove to be effective;

we may discover that a product candidate may cause harmful side effects;

the results may not replicate the results of earlier, smaller trials;

we or the FDA or similar foreign regulatory authorities may suspend the trials;

the results may not be statistically significant;

patient recruitment may be slower than expected;

patients may drop out of the trials; and

regulatory requirements may change.

For example, there is uncertainty regarding future development of indiplon as described below under the risk factor entitled *There is uncertainty regarding future development of our product candidate, indiplon, and we may not be able to meet the requirements to receive regulatory approvals for it.*

In addition, late stage clinical trials are often conducted with patients having the most advanced stages of disease. During the course of treatment, these patients can die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested but which can nevertheless adversely affect clinical trial results. Any failure or substantial delay in completing clinical trials for our product candidates may severely harm our business.

If we cannot raise additional funding, we may be unable to complete development of our product candidates.

We may require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses and to pursue regulatory approvals for product candidates, for the costs involved in filing and prosecuting patent application and enforcing or defending patent claims, if any, as well as costs associated with litigation matters, product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We believe that our existing capital resources, together with investment income, and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, these resources might be insufficient to conduct research and development programs as planned. If we cannot obtain adequate funds, we may be required to curtail significantly one or more of our research and development programs or obtain funds through additional arrangements with corporate collaborators or others that may require us to relinquish rights to some of our technologies or product candidates.

Our future capital requirements will depend on many factors, including:

continued scientific progress in our research and development programs;

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the magnitude of our research and development programs;

progress with preclinical testing and clinical trials;

the time and costs involved in obtaining regulatory approvals;

the costs involved in filing and pursuing patent applications and enforcing patent claims;

competing technological and market developments;

the establishment of additional strategic alliances;

the cost of commercialization activities and arrangements, including manufacturing of our product candidates; and

the cost of product in-licensing and any possible acquisitions.

We intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. For example, we have an effective shelf registration statement on file with the Securities and Exchange Commission which allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to $150 million. In addition, we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. Accordingly, additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

Our restructuring activities could result in management distractions, operational disruptions and other difficulties.

In order to focus efforts on our clinical programs, we initiated restructuring activities in an effort to reduce operating costs, including a work force reduction announced in May 2009. Employees whose positions were eliminated in connection with this reduction may seek future employment with our competitors. Although all employees are required to sign a confidentiality agreement with us at the time of hire, we cannot assure you that the confidential nature of our proprietary information will be maintained in the course of such future employment. We cannot assure you that we will not undertake additional restructuring activities, that any of our restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from our previous or future restructuring plans. In addition, if we continue to reduce our workforce, it may adversely impact our ability to respond rapidly to any new growth opportunities.

We also entered into a December 2008 amendment to our facilities lease, under which our landlord will seek to enter into leases with replacement tenants for portions of the front building of our corporate headquarters, thereby reducing our rent under the lease. Our landlord may not be successful in entering into leases with replacement tenants on favorable terms, or at all. Any additional restructuring efforts could divert the attention of our management away from our operations, harm our reputation and increase our expenses. If we are unable to lease our front building, we will continue to incur significant expense which will limit the resources we can devote to our development programs.

There is uncertainty regarding future development of our product candidate, indiplon, and we may not be able to meet the requirements to receive regulatory approvals for it.

On December 12, 2007 we received an action letter from the FDA stating that indiplon 5mg and 10mg capsules are approvable (2007 FDA Approvable Letter). The 2007 FDA Approvable Letter acknowledged that our resubmitted NDA for indiplon 5mg and 10mg capsules had addressed the issues raised in a previous approvable letter, but set forth new requirements. The new requirements set forth in the 2007 FDA Approvable Letter are the following: (i) an

objective/subjective clinical trial in the elderly, (ii) a safety study assessing the rates of adverse events occurring with indiplon when compared to a marketed product and (iii) a preclinical study to evaluate indiplon administration during the third trimester of pregnancy. After receipt of the 2007 FDA Approvable Letter, we ceased all indiplon clinical development activities in the United States as well as all pre-commercialization activities. We met with the FDA in July 2008 to discuss the 2007 FDA Approvable Letter and we are awaiting the finalization of the written minutes of this meeting from the FDA.

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The process of preparing and resubmitting the NDA for indiplon would require significant resources and could be time consuming and subject to unanticipated delays and cost. As a result of the 2007 FDA Approvable Letter, there is a significant amount of uncertainty regarding the future development of indiplon. Should the NDA be refiled, the FDA could again refuse to approve the NDA, or could still require additional data analysis or clinical trials, which would require substantial expenditures by us and would further delay the approval process. Even if our indiplon NDA is approved, the FDA may determine that our data do not support elements of the labeling we have requested. In such a case, the labeling actually granted by the FDA could limit the commercial success of the product. The FDA could require Phase IV, or post-marketing, trials to study the long-term effects of indiplon and could withdraw its approval based on the results of those trials. The FDA could also require a Risk Evaluation and Mitigation Strategy (REMS) program for indiplon that could limit the commercial success of the product. We face the risk that for any of the reasons described above, as well as other reasons set forth herein, indiplon may never be approved by the FDA or commercialized anywhere in the world.

If we determine that it is impractical or we are unable to refile the NDA, or the FDA refuses to accept or approve the resubmitted NDA for any reason or we experience a further delay in approval and subsequent commercialization of indiplon, our business and reputation may be harmed and our stock price could decline.

We have a history of losses and expect to incur losses and negative operating cash flows for the near future, and we may never achieve sustained profitability.

Since our inception, we have incurred significant net losses, including net losses of $88.6 million and $207.3 million for the years ended December 31, 2008 and 2007, respectively. As a result of ongoing operating losses, we had an accumulated deficit of $703.3 million and $614.7 million as of December 31, 2008 and 2007, respectively. We do not expect to be profitable for the year ending December 31, 2009 or the foreseeable future.

We have not yet obtained regulatory approvals of any products and, consequently, have not generated revenues from the sale of products. Even if we succeed in developing and commercializing one or more of our drugs, we may not be profitable. We also expect to continue to incur significant operating and capital expenditures as we:

- seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our drugs;
- in-license or acquire new product development opportunities;
- implement additional internal systems and infrastructure; and
- hire additional clinical, scientific and marketing personnel.

We also expect to experience negative cash flow for the near future as we fund our operating losses, in-licensing or acquisition opportunities, and capital expenditures. We will need to generate significant revenues to achieve and maintain profitability and positive cash flow. We may not be able to generate these revenues, and we may never achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the market price of our common stock. Even if we become profitable, we cannot assure you that we would be able to sustain or increase profitability on a quarterly or annual basis.

Because our operating results may vary significantly in future periods, our stock price may decline.

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our revenues are unpredictable and may fluctuate, among other reasons, due to our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing and contract research payments. A high portion of our costs are predetermined on an annual basis, due in part to our significant research and development costs. Thus, small declines in revenue could disproportionately affect operating results in a quarter. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline.

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We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, we could lose our rights to those technologies and drug candidates.

We are dependent on licenses from third parties for some of our key technologies. These licenses typically subject us to various commercialization, reporting and other obligations. If we fail to comply with these obligations, we could lose important rights. For example, we have licensed indiplon from DOV Pharmaceutical, Inc. (DOV). In addition, we license some of the core technologies used in our collaborations from third parties, including the CRF receptor we license from The Salk Institute and use in our CRF_1 program, and urocortin 2 which we license from Research Development Foundation. Other in-licensed technologies, such as the GnRH receptor we license from Mount Sinai School of Medicine, will be important for future collaborations for our *elagolix* program. If we were to default on our obligations under any of our licenses, we could lose some or all of our rights to develop, market and sell products covered by these licenses. Likewise, if we were to lose our rights under a license to use proprietary research tools, it could adversely affect our existing collaborations or adversely affect our ability to form new collaborations. We also face the risk that our licensors could, for a number of reasons, lose patent protection or lose their rights to the technologies we have licensed, thereby impairing or extinguishing our rights under our licenses with them.

Because the development of our product candidates is subject to a substantial degree of technological uncertainty, we may not succeed in developing any of our product candidates.

All of our product candidates are in research, clinical development or in registration with the FDA. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

be found ineffective or cause harmful side effects during preclinical studies or clinical trials;

fail to receive necessary regulatory approvals on a timely basis or at all;

be precluded from commercialization by proprietary rights of third parties;

be difficult to manufacture on a large scale; or

be uneconomical to commercialize or fail to achieve market acceptance.

If any of our products encounters any of these potential problems, we may never successfully market that product.

We have limited marketing experience, sales force or distribution capabilities, and if our products are approved, we may not be able to commercialize them successfully.

Although we do not currently have any marketable products, our ability to produce revenues ultimately depends on our ability to sell our products if and when they are approved by the FDA. We currently have limited experience in marketing and selling pharmaceutical products. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues will suffer.

The independent clinical investigators and contract research organizations that we rely upon to conduct our clinical trials may not be diligent, careful or timely, and may make mistakes, in the conduct of our trials.

We depend on independent clinical investigators and contract research organizations (CROs) to conduct our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, it may delay or prevent the approval of our FDA applications and our introduction of new drugs. The CROs we contract with for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our

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products. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may compete with us. If independent investigators and CROs assist our competitors at our expense, it could harm our competitive position.

We have no manufacturing capabilities. If third-party manufacturers of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed and our costs may rise.

We have in the past utilized, and intend to continue to utilize, third-party manufacturers to produce the drug compounds we use in our clinical trials and for the potential commercialization of our future products. We have no experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Consequently, we depend on, and will continue to depend on, several contract manufacturers for all production of products for development and commercial purposes. If we are unable to obtain or retain third-party manufacturers, we will not be able to develop or commercialize our products. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations. Our third-party manufacturers might not comply with FDA regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. Our reliance on contract manufacturers also exposes us to the following risks:

- contract manufacturers may encounter difficulties in achieving volume production, quality control and quality assurance, and also may experience shortages in qualified personnel. As a result, our contract manufacturers might not be able to meet our clinical schedules or adequately manufacture our products in commercial quantities when required;

- switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all;

- our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store or distribute our products; and

- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA, and other agencies to ensure strict compliance with good manufacturing practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers compliance with these regulations and standards.

Our current dependence upon third parties for the manufacture of our products may harm our profit margin, if any, on the sale of our future products and our ability to develop and deliver products on a timely and competitive basis.

If we are unable to retain and recruit qualified scientists or if any of our key senior executives discontinues his or her employment with us, it may delay our development efforts.

We are highly dependent on the principal members of our management and scientific staff. The loss of any of these people could impede the achievement of our development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to our success. We may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, pharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy. All of our consultants are employed by employers other than us. They may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is commonplace in the biotechnology industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we 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. Even if we are successful in defending against these claims, litigation could

result in substantial costs and be a distraction to management.

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Governmental and third-party payors may impose sales and pharmaceutical pricing controls on our products that could limit our product revenues and delay profitability.

The continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means may reduce our potential revenues. These payors efforts could decrease the price that we receive for any products we may develop and sell in the future. In addition, third-party insurance coverage may not be available to patients for any products we develop. If government and third-party payors do not provide adequate coverage and reimbursement levels for our products, or if price controls are enacted, our product revenues will suffer.

If physicians and patients do not accept our products, we may not recover our investment.

The commercial success of our products, if they are approved for marketing, will depend upon the acceptance of our products as safe and effective by the medical community and patients.

The market acceptance of our products could be affected by a number of factors, including:

the timing of receipt of marketing approvals;

the safety and efficacy of the products;

the success of existing products addressing our target markets or the emergence of equivalent or superior products; and

the cost-effectiveness of the products.

In addition, market acceptance depends on the effectiveness of our marketing strategy, and, to date, we have very limited sales and marketing experience or capabilities. If the medical community and patients do not ultimately accept our products as being safe, effective, superior and/or cost-effective, we may not recover our investment.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq rules, are creating uncertainty for companies such as ours. These laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting requires the commitment of significant financial and managerial resources. We expect these efforts to require the continued commitment of significant resources. If we fail to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the Securities and Exchange Commission. Any such action could adversely affect our financial results and the market price of our common stock.

The price of our common stock is volatile.

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Over the course of the last 12 months, the price of our common stock has ranged from approximately $2 per share to approximately $6 per share. The market price of our common stock may fluctuate in response to many factors, including:

the results of our clinical trials;

developments concerning our strategic alliance agreements;

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announcements of technological innovations or new therapeutic products by us or others;

general economic and market conditions;

developments in patent or other proprietary rights;

developments related to the FDA approval process for indiplon;

future sales of our common stock by existing stockholders;

comments by securities analysts;

fluctuations in our operating results;

government regulation;

health care reimbursement;

failure of any of our product candidates, if approved, to achieve commercial success; and

public concern as to the safety of our drugs.

Negative conditions in the global credit markets may impair the liquidity of a portion of our investment portfolio.

Our investment securities consist of auction rate securities, corporate debt securities and government agency securities. As of March 31, 2009, our long-term investments included (at par value) $22.6 million of auction rate securities. All of our 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 auction rate securities have experienced failed auctions due to lack of liquidity at the time their interest rates were to reset. The recent negative conditions in the global credit markets have prevented some investors from liquidating their holdings, including their holdings of auction rate securities. As a result, certain of these types of securities are not fully liquid and we could be required to hold them until they are redeemed by the issuer, a future auction for these securities is successful, another secondary market evolves for these securities, or they mature. In the event we need to access the funds that are in an illiquid state, we may not be able to do so without a potential loss of principal. As of March 31, 2009, the carrying value of all auction rate securities had been reduced by $5.1 million, from $22.6 million to $17.5 million, reflecting an estimated change in fair market value due primarily to a lack of liquidity. Although the auction rate securities continue to pay interest according to their stated terms, based on valuation models, we have recorded a unrealized loss for an other-than-temporary change in valuation of $5.1 million. If the credit ratings of the security issuers deteriorate or if uncertainties in these markets continue and any decline in market value is determined to be other-than-temporary, we would be required to adjust the carrying value of the investment through an impairment charge, which could negatively affect our financial condition, cash flow and reported earnings.

Risks Related to Our Industry

We may not receive regulatory approvals for our product candidates or approvals may be delayed.

Regulation by government authorities in the United States and foreign countries is a significant factor in the development, manufacture and marketing of our proposed products and in our ongoing research and product development activities. Any failure to receive the regulatory approvals necessary to commercialize our product candidates would harm our business. The process of obtaining these approvals and the subsequent compliance with federal and state statutes and regulations require spending substantial time and financial resources. If we fail or our collaborators or licensees fail to obtain or maintain, or encounter delays in obtaining or maintaining, regulatory approvals, it could adversely affect the marketing of any products we develop, our ability to receive product or royalty revenues, our recovery of prepaid royalties, and our liquidity and capital resources. All of our products are in research and development, and we have not yet received regulatory approval to commercialize any product from the FDA or

any other regulatory body. In addition, we have limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain such approvals.

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In particular, human therapeutic products are subject to rigorous preclinical testing and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish the product candidate s safety and efficacy. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies. Any FDA or other regulatory approval of our product candidates, once obtained, may be withdrawn. If our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments.

We face intense competition, and if we are unable to compete effectively, the demand for our products, if any, may be reduced.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies.

Competition may also arise from, among other things:

other drug development technologies;

methods of preventing or reducing the incidence of disease, including vaccines; and

new small molecule or other classes of therapeutic agents.

Developments by others may render our product candidates or technologies obsolete or noncompetitive.

We are performing research on or developing products for the treatment of several disorders including endometriosis, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia, and other neurological and endocrine related diseases and disorders, and there are a number of competitors to products in our research pipeline. If one or more of our competitors products or programs are successful, the market for our products may be reduced or eliminated.

Compared to us, many of our competitors and potential competitors have substantially greater:

capital resources;

research and development resources, including personnel and technology;

regulatory experience;

preclinical study and clinical testing experience;

manufacturing and marketing experience; and

production facilities.

If we are unable to protect our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

Our success will depend on our ability to, among other things:

obtain patent protection for our products;

preserve our trade secrets;

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prevent third parties from infringing upon our proprietary rights; and

operate without infringing upon the proprietary rights of others, both in the United States and internationally.

Because of the substantial length of time and expense associated with bringing new products through the development and regulatory approval processes in order to reach the marketplace, the pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Accordingly, we intend to seek patent protection for our proprietary technology and compounds. However, we face the risk that we may not obtain any of these patents and that the breadth of claims we obtain, if any, may not provide adequate protection of our proprietary technology or compounds.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our commercial collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our commercial collaborators and consultants. However, if our employees, commercial collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors.

In addition, although we own a number of patents, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In addition, in an infringement proceeding a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. Interference proceedings declared by the United States Patent and Trademark Office (USPTO) may be necessary to determine the priority of inventions with respect to our patent applications or those of our licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to management. We cannot assure you that we will be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

The technologies we use in our research as well as the drug targets we select may infringe the patents or violate the proprietary rights of third parties.

We cannot assure you that third parties will not assert patent or other intellectual property infringement claims against us or our collaborators with respect to technologies used in potential products. If a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party s intellectual property unless that party grants us or our collaborators rights to use its intellectual property. In such cases, we could be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if our collaborators or we were able to obtain rights to the third party s intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

We face potential product liability exposure far in excess of our limited insurance coverage.

The use of any of our potential products in clinical trials, and the sale of any approved products, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of $10 million per occurrence and $10 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable

cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for product candidates in development,

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but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, juries have awarded large judgments in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us would decrease our cash reserves and could cause our stock price to fall.

Our activities involve hazardous materials, and we may be liable for any resulting contamination or injuries.

Our research activities involve the controlled use of hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. If an accident occurs, a court may hold us liable for any resulting damages, which may harm our results of operations and cause us to use a substantial portion of our cash reserves, which would force us to seek additional financing.

ITEM 6. EXHIBITS

3.1 Restated Certificate of Incorporation (1)

3.2 Certificate of Amendment to Certificate of Incorporation (2)

3.3 Bylaws (1)

3.4 Certificate of Amendment of Bylaws (3)

3.5 Certificate of Amendment of Bylaws (4)

4.1 Form of Common Stock Certificate (1)

31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934.

31.2 Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934.

32* Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference to the Company s Registration Statement on Form S-1 (Registration No. 333-03172)

(2) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on August 9, 2006

(3)

Incorporated by reference to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 1997 filed on April 10, 1998

(4) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on August 9, 2004

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Neurocrine Biosciences, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: May 5, 2009

/s/ Timothy P. Coughlin
Timothy P. Coughlin
Vice President and Chief Financial Officer
(Duly authorized officer and Principal Financial Officer)