NEUROCRINE BIOSCIENCES INC
Form 10-Q
May 02, 2008

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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 AND EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2008

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND 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.)
12790 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 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 smaller reporting company)

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

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 38,421,043 as of April 25, 2008.

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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, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 107,639	$ 99,664
Short-term investments, available-for-sale	42,106	79,721
Receivables under collaborative agreements	12	27
Other current assets	2,446	3,536
Total current assets	152,203	182,948
Property and equipment, net	80,672	82,598
Restricted cash	6,415	6,399
Other non-current assets	4,594	4,709
Total assets	$ 243,884	$ 276,654
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,408	$ 3,776
Accrued liabilities	12,620	21,717
Deferred revenues	2,919	2,928
Current portion of long-term debt	1,025	1,486
Total current liabilities	17,972	29,907
Long-term deferred revenues	13,865	14,595
Leaseback financing obligation	108,745	108,745
Other liabilities	4,636	4,710
Total liabilities	145,218	157,957
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 38,395,307 as of March 31, 2008 and 38,273,979 as of December 31, 2007	38	38
Additional paid-in capital	735,731	733,542
Accumulated other comprehensive loss	(1,376)	(233)
Accumulated deficit	(635,727)	(614,650)

Total stockholders equity	98,666	118,697
Total liabilities and stockholders equity	$ 243,884	$ 276,654

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,	
	2008	**2007**
Revenues:		
Sponsored research and development	$ 12	$ 86
License fees and milestones	1,730	
Grant revenue	9	18
Total revenues	1,751	104
Operating expenses:		
Research and development	14,227	19,061
General and administrative	8,286	8,317
Total operating expenses	22,513	27,378
Loss from operations	(20,762)	(27,274)
Other income and (expense):		
Interest income and other income	1,606	2,424
Interest expense	(1,921)	(870)
Total other (expense) income	(315)	1,554
Net loss	$(21,077)	$(25,720)
Net loss per common share:		
Basic and diluted	$ (0.55)	$ (0.68)
Shares used in the calculation of net loss per common share:		
Basic and diluted	38,330	37,908

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,	
	2008	**2007**
CASH FLOW FROM OPERATING ACTIVITIES		
Net loss	$ (21,077)	$ (25,720)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,067	2,561
Gain on sale of assets	(34)	
Deferred revenues	(739)	36
Share-based compensation expense	2,189	2,409
Change in operating assets and liabilities:		
Accounts receivable and other current assets	1,105	7,532
Other non-current assets	(139)	76
Accounts payable and accrued liabilities	(11,465)	(1,717)
Other non-current liabilities	(74)	(30)
Net cash used in operating activities	(28,167)	(14,853)
CASH FLOW FROM INVESTING ACTIVITIES		
Purchases of short-term investments	(9,984)	(38,996)
Sales/maturities of short-term investments	46,688	52,555
Deposits and restricted cash	6	
Sale of property and equipment	174	
Purchases of property and equipment	(281)	(65)
Net cash provided by investing activities	36,603	13,494
CASH FLOW FROM FINANCING ACTIVITIES		
Issuance of common stock		73
Principal payments on debt	(461)	(1,238)
Net cash used in financing activities	(461)	(1,165)
Net increase (decrease) in cash and cash equivalents	7,975	(2,524)
Cash and cash equivalents at beginning of the period	99,664	80,981
Cash and cash equivalents at end of the period	$ 107,639	$ 78,457

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 audited financial statements and notes thereto for the year ended December 31, 2007 included in our Annual Report on Form 10-K for the year ended December 31, 2007 filed with the SEC.

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, irritable bowel syndrome, anxiety, depression, pain, diabetes, insomnia 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.

3. IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 159, The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115 (SFAS 159). SFAS 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, e.g., debt issue costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS 159, changes in fair value are recognized in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and was adopted by the Company in the first quarter of 2008. The adoption of SFAS 159 did not have a material impact on its consolidated results of operations and financial condition as the fair value option was not elected for any of the Company s financial assets or financial liabilities.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which a company measures assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any

new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and was adopted by the Company in the first quarter of 2008. The adoption of SFAS 157 did not have a material impact on its consolidated results of operations and financial condition.

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In June 2007, the FASB ratified EITF Issue No. 07-3 (EITF No. 07-3), Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities , which requires nonrefundable advance payments for goods and services that will be used or rendered for future research and development activities to be deferred and capitalized. These amounts will be recognized as expense in the period that the related goods are delivered or the related services are performed. EITF No. 07-3 is effective for fiscal years beginning after December 15, 2007. The Company adopted the provisions of EITF No. 07-3 on January 1, 2008 and the adoption of EITF No. 07-3 did not have a material impact on its consolidated results of operations and financial condition.

4. SHARE-BASED COMPENSATION

The Company s net loss for the three months ended March 31, 2008 and 2007 includes $2.2 million and $2.4 million, respectively, of compensation expense related to the Company s share-based compensation awards. As of March 31, 2008, total unrecognized estimated compensation cost related to non-vested stock options and non-vested restricted stock units (RSUs) granted prior to that date was $6.6 million and $10.8 million, respectively, which is expected to be recognized over a weighted average period of approximately 2.2 years and 2.6 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,	
	2008	**2007**
General and administrative	$ 1.3	$ 1.3
Research and development	0.9	1.1

Cash received from stock option exercises for the three months ended March 31, 2007 was $73,000. There were no stock option exercises for the three months ended March 31, 2008. During the first three months of 2008, the Company issued approximately 121,000 shares of common stock upon vesting of RSUs.

Stock Option Assumptions

The exercise price of all options granted during the three month periods ended March 31, 2008 and 2007 was equal to the closing price of the Company s common stock on the date of grant. The estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for option grants during the three months ended March 31, 2008 and 2007:

	Three Months Ended March 31,	
	2008	**2007**
Risk-free interest rate	2.49%	4.79%
Expected volatility of common stock	68.74%	65.76%
Dividend yield	0.0%	0.0%
Expected option term	4.75 years	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.

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5. 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.

6. FAIR VALUE MEASUREMENTS

As described in Note 3, the Company adopted 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.

The Company s short-term investments at March 31, 2008 include (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. 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). Additionally, all of the Company s auction rate securities maintain the highest credit rating of AAA.

At present, in the event the Company needs to access the funds that are in an illiquid state, it 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, until they are redeemed by the issuer or they mature. At this time, the Company has not obtained sufficient evidence to conclude that these auction rate securities will not be settled in the short term, although the market for these investments is presently uncertain. If the Company is unable to sell these securities in the market or they are not redeemed, then the Company could be required to hold them to maturity. The Company does not have a need to access these funds for operational purposes in the foreseeable future. The Company will continue to monitor and evaluate these investments on an ongoing basis for impairment or for the need to reclassify them as long-term investments. Although the auction rate security investments continue to pay interest according to their stated terms, based on valuation models the Company recorded an unrealized loss of approximately $1.0 million in accumulated other comprehensive loss as a reduction in shareholders equity, reflecting adjustments to auction rate security holdings that the Company has concluded have a temporary decline in value due to a lack of liquidity in the global credit markets. The carrying value in short-term investments for these auction rate securities at March 31, 2008 is approximately $21.6 million.

The valuation of the Company s ARS 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 or other type of valuation model as of March 31, 2008. The key driver of the valuation models is the expected term. Changes to this assumption one year in either direction did not have a material impact on our valuation. Other items these analyses consider are the collateralization underlying the security investments, the creditworthiness of the counterparty, the timing of expected future cash flows, and the expectation of the next time the security is expected to have a successful auction. These securities were also compared, when possible, to other observable market data with similar characteristics to the securities held by the Company.

Factors that may impact the Company s valuation 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.

Assets measured at fair value as of March 31, 2008 are classified in the table below in one of the three categories described above (in thousands):

		Fair Value Measurements at Reporting Date Using		
Description	**3/31/2008**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Money market funds	$ 78,854	$ 78,854		
Commercial paper	29,713	29,713		
Corporate debt securities	13,458	13,458		
U.S. Government securities	13,435	13,435		
Auction rate securities (1)	21,625			$ 21,625
Total	$ 157,085	$ 135,460	$	$ 21,625

Activity for assets measured at fair value during the three month period ended March 31, 2008 using significant unobservable inputs (Level 3) is presented in the table below (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
Beginning balance	$
Total gains or losses (realized/unrealized) included in other comprehensive income	(975)
Transfers in and/or out of Level 3	22,600
Ending balance	$ 21,625
Amount of total gains or losses for the period included in earnings attributable to the change in unrealized gains or losses relating to assets still held at the reporting date	$

(1) The Company estimated the fair value of these auction rate securities 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; and (iv) its market required rate of return.

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7. 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.

8. IMPAIRMENT OF LONG-LIVED ASSETS

In accordance with SFAS No. 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.

9. 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. The Company expects this restructuring to reduce annual expenses by approximately $19.0 million.

As of March 31, 2008, the Company had a remaining balance of approximately $3.5 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 quarter of 2008 are as follows (in thousands):

Accrual balance as of December 31, 2007	$ 6,924
Payments	(5,520)
Additional accruals	2,357
Adjustments	(213)
Accrual balance as of March 31, 2008	$ 3,548

10. RETENTION PROGRAM

On February 27, 2008, the Board approved an employee retention program (Retention Program) to provide the Company with a mechanism to retain its non-officer and executive officer employees who were not subject to the Company s December 2007 restructuring program. As part of the Retention Program, the Board approved a one-time cash retention payment totaling $3.2 million, 60% of which was paid in the first quarter of 2008 and the remaining 40% of which is payable at the end of 2008, assuming such individual remains in good standing as an employee at such time. In addition, the Board approved the issuance of RSUs covering an aggregate of 1,203,000 shares and stock options covering an aggregate of 501,000 shares to its executive officers and certain employees, all of which were issued in the first quarter of 2008.

11. LOSS PER COMMON SHARE

The Company computes net loss per share in accordance with SFAS No. 128, Earnings Per Share. Under the provisions of SFAS No. 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 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 0.1 million and 1.6 million for the three months ended March 31, 2008 and 2007, respectively.

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12. COMPREHENSIVE LOSS

Comprehensive loss is calculated in accordance with SFAS No. 130, Comprehensive Income. SFAS No. 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 short-term investments. For the three months ended March 31, 2008 and 2007, comprehensive loss was $22.2 million and $25.5 million, respectively.

13. 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 and 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.

14. 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, which 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.

15. 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. FIN 48 is effective for fiscal years beginning after December 15, 2006.

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, 2007 and at March 31, 2008, and has not recognized interest and/or penalties in the statement of operations for the first quarter of 2008.

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.

The adoption of FIN 48 did not impact the Company s financial condition, results of operations or cash flows. At January 1, 2008, the Company had net deferred tax assets of $65.8 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 $194.4 million and research and development credits of $37.1 million generated through 2007 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits under FIN 48. 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.

16. LITIGATION

On June 19, 2007, Construction Laborers Pension Trust of Greater St. Louis filed a purported class action lawsuit in the United States District Court for the Southern District of California under the caption Construction Laborers Pension Trust of Greater St. Louis v. Neurocrine Biosciences, Inc., et al., 07-cv-1111-IEG-RBB. On June 26, 2007, a second purported class action lawsuit with similar allegations was also filed. On October 16, 2007, both lawsuits were consolidated into one purported class action under the caption In re Neurocrine Biosciences, Inc. Securities Litigation, 07-cv-1111-IEG-RBB. The court also selected lead plaintiffs and ordered them to file a consolidated complaint. On November 30, 2007, lead plaintiffs filed the Consolidated Amended Complaint (CAC), which is

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now the operative complaint in the litigation. The CAC alleges, among other things, that the Company and certain of its officers and directors violated federal securities laws by making allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of indiplon in the 15 mg dosage unit. On January 11, 2008, the Company and the individual defendants filed a motion to dismiss the CAC. A hearing on the motion was conducted on April 22, 2008. No ruling has been issued at this time.

In addition, on June 25, 2007, a shareholder derivative complaint was filed in the Supreme Court of the State of California for the County of San Diego by Ralph Lipeles under the caption, Lipeles v. Lyons. The complaint was brought purportedly on our behalf against certain current and former officers and directors and alleges, among other things, that the named officers and directors breached their fiduciary duties by directing us to make allegedly false statements about the progress toward FDA approval and the potential for market success of indiplon in the 15 mg dosage unit. All proceedings in this matter have been stayed pending resolution of the motion to dismiss the federal class action lawsuit.

The Company intends to take all appropriate action in responding to all of the complaints. Due to the uncertainty of the ultimate outcome of these matters, the impact, if any, on the Company s future financial results is not subject to reasonable estimate as of March 31, 2008.

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, 2007 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, 2007.

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, irritable bowel syndrome, anxiety, depression, pain, diabetes, insomnia and other neurological and endocrine related diseases and disorders. 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 collaborations with pharmaceutical companies for two of our programs. Our lead clinical development program, GnRH, is a drug candidate for the treatment of endometriosis.

In December 2007, we announced a restructuring program to implement cost containment measures and to focus research and development efforts. As a result, we reduced our research and development and general and administrative staff in San Diego by approximately 125 employees. In connection with this restructuring, we recorded a one-time charge of approximately $6.9 million in the fourth quarter of 2007, of which $4.9 million was included in research and development expense and $2.0 million was included in general and administrative expense. 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, we incurred an additional $2.1 million charge (net) for severance related to certain executives and other personnel departing the Company. We expect this restructuring to reduce annual expenses by approximately $19.0 million.

On February 27, 2008, we approved an employee retention program (Retention Program) to provide us with a mechanism to retain our non-officer and executive officer employees who were not subject to our December 2007 restructuring program. As part of the Retention Program, we approved a one-time cash retention payment totaling $3.2 million; 60% of which was paid in the first quarter of 2008 and the remaining 40% of which is payable at the end of 2008, assuming such individual remains in good standing as an employee at such time. In addition, we approved the issuance of restricted stock units (RSUs) covering an aggregate of 1,203,000 shares and stock options covering an

aggregate of 501,000 shares to our executive officers and certain employees, all of which were issued in the first quarter of 2008.

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 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:

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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, and 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, which 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 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 related asset, which is generally determined based on the present value of the expected future cash flows.

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 Statement of Financial Accounting Standards No. 123 (SFAS 123R), Share-Based Payment. Share-based compensation expense recognized under SFAS 123R for the three months ended March 31, 2008 and 2007 was $2.2 million and $2.4 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 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.

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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.

THREE MONTHS ENDED MARCH 31, 2008 AND 2007

Revenues were $1.8 million for the first quarter of 2008 compared with $0.1 million for the respective period last year. The increase in revenues for the three months ended March 31, 2008, compared with the respective period in 2007, is primarily from revenues recognized in 2008 under our collaboration agreements with GlaxoSmithKline (GSK) and Dainippon Sumitomo Pharma Co. Ltd (DSP). During the first quarter of 2008, we recognized a $1.0 million milestone from GSK related to clinical advancements of our CRF program. During the first quarter of 2008, we also recognized $0.7 million in revenue under our collaboration agreement with DSP from amortization of up-front licensing fees. We recognized $74,000 and $12,000 in revenue in the form of sponsored development funding from GSK and Pfizer, respectively, during the first quarter of 2007.

Research and development expenses decreased to $14.2 million for the first quarter of 2008 compared with $19.1 million for the respective period in 2007. This decrease in research and development expenses is primarily due to cost savings related to our restructuring during the fourth quarter of 2007, coupled with lower external development costs. The decrease in staff levels reduced personnel costs by $3.3 million, from $8.5 million in the first quarter of 2007, to $5.2 million in the first quarter of 2008. Additionally, laboratory costs decreased by $0.5 million in the first quarter of 2008 compared to the same period in 2007. External development costs decreased by $0.9 million to $4.1 million in the first quarter of 2008 compared to $5.0 million in the same period last year. External development spending on our GnRH program increased from $3.4 million in the first quarter of 2007 to $3.7 million in the first quarter of 2008. The increase in our GnRH external development spending was offset by decreased costs in other external development programs. We currently have eight programs in various stages of research and development, including five programs in clinical development.

General and administrative expenses were $8.3 million for the first quarter of 2008 compared with $8.3 million during the same period last year. The Company incurred $2.2 million of restructuring charges in the first quarter of 2008. This cost was offset by cost savings related to the restructuring implemented in the fourth quarter of 2007.

Other income (expense) decreased from $1.6 million during the first quarter of 2007 to $(0.3) million for the first quarter of 2008. The decrease resulted primarily from rent payments made under our facilities sale-leaseback agreement that are recorded as interest expense under sale-leaseback accounting rules. Additionally, investment income for the first quarter of 2008 is lower than in the prior year period, primarily due to lower interest rates.

Net loss for the first quarter of 2008 was $21.1 million, or $0.55 per share, compared to $25.7 million, or $0.68 per share, for the same period in 2007. This decrease in net loss is due primarily to a reduction in expenses as a result of our restructuring program implemented in the fourth quarter of 2007.

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 the results 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 quarters ended March 31, 2008 and 2007.

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, 2008, our cash, cash equivalents, and short-term investments totaled $149.7 million compared with $179.4 million at December 31, 2007. The decrease in cash balances at March 31, 2008 resulted primarily from our net loss of $21.1 million and cash payments related to our December 2007 restructuring program of $5.5 million, and a reduction in accounts payable from the prior year of approximately $6.0 million.

Our short-term investments at March 31, 2008 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. However, we now earn a higher interest rate according to the terms of these 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). Additionally, all of our auction rate securities maintain the highest credit rating of AAA.

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, until they are redeemed by the issuer or they mature. At this time, we have not obtained sufficient evidence to conclude that these auction rate securities will not be settled in the short term, although the market for these investments is presently uncertain. 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 have a need to access these funds for operational purposes in the foreseeable future. We will continue to monitor and evaluate these investments on an ongoing basis for impairment or for the need to reclassify them as long-term investments. Although the auction rate security investments continue to pay interest according to their stated terms, based on valuation models of the individual securities, we recorded an unrealized loss of approximately $1.0 million in accumulated other comprehensive loss as a reduction in shareholders equity, reflecting adjustments to auction rate security holdings that we concluded have a temporary decline in value due to a lack of liquidity in the global credit markets. The carrying value in short-term investments for these auction rate securities at March 31, 2008 is $21.6 million.

The valuation of our ARS 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 or other type of valuation model as of March 31, 2008. The key driver of the valuation models is the expected term. Changes to this assumption one year in either direction did not have a material impact on our valuation. Other items these analyses consider are the collateralization underlying the security investments, the creditworthiness of the counterparty, the timing of expected future cash flows, and the expectation of the next time the security is expected to have a successful auction. These securities were also compared, when possible, to other observable market data with similar characteristics to the securities held by us.

Factors that may impact our valuation 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.

Net cash used in operating activities during the first quarter of 2008 was $28.2 million compared with $14.9 million during the same period last year. This fluctuation resulted primarily from $11.5 million in payments made to reduce accounts payable and accrued liabilities (including accrued severance) in the first quarter of 2008 versus only $1.7 million in corresponding payments made for the same period in 2007 and by a reduction in accounts receivable in the first three months of 2007 of $7.5 million compared to a corresponding decrease of only $1.1 million in the same period during 2008.

Net cash provided by investing activities during the first quarter of 2008 was $36.6 million compared to $13.5 million for the first quarter of 2007. 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.

Net cash used in financing activities during the first quarter of 2008 was $0.5 million compared to $1.2 million for the respective period last year. This fluctuation resulted primarily from cash payments made on outstanding debt obligations.

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

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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. 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. 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-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 average maturity of our investments does not exceed 36 months. If a 10% change in interest rates were to have occurred on March 31, 2008, 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, we have concluded that we do not have a material financial market interest rate risk exposure.

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 Securities and Exchange Commission 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 decision 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.

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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 1. LEGAL PROCEEDINGS

On June 19, 2007, Construction Laborers Pension Trust of Greater St. Louis filed a purported class action lawsuit in the United States District Court for the Southern District of California under the caption Construction Laborers Pension Trust of Greater St. Louis v. Neurocrine Biosciences, Inc., et al., 07-cv-1111-IEG-RBB. On June 26, 2007, a second purported class action lawsuit with similar allegations was also filed. On October 16, 2007, both lawsuits were consolidated into one purported class action under the caption In re Neurocrine Biosciences, Inc. Securities Litigation, 07-cv-1111-IEG-RBB. The court also selected lead plaintiffs and ordered them to file a consolidated complaint. On November 30, 2007, lead plaintiffs filed the Consolidated Amended Complaint (CAC), which is now the operative complaint in the litigation. The CAC alleges, among other things, that the Company and certain of its officers and directors violated federal securities laws by making allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of indiplon in the 15 mg dosage unit. On January 11, 2008, Neurocrine and the individual defendants filed a motion to dismiss the CAC. A hearing on the motion was conducted on April 22, 2008. No ruling has been issued at this time.

In addition, on June 25, 2007, a shareholder derivative complaint was filed in the Superior Court of the State of California for the County of San Diego by Ralph Lipeles under the caption, Lipeles v. Lyons. The complaint was brought purportedly on our behalf against certain current and former officers and directors and alleges, among other things, that the named officers and directors breached their fiduciary duties by directing us to make allegedly false statements about the progress toward FDA approval and the potential for market success of indiplon in the 15mg dosage unit. All proceedings in this matter have been stayed pending resolution of the motion to dismiss the federal class action lawsuit.

The Company intends to take all appropriate action in responding to all of the complaints. Due to the uncertainty of the ultimate outcome of these matters, the impact, if any, on the Company s future financial results is not subject to reasonable estimate as of March 31, 2008.

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, 2007, 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

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;

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the results may not be statistically significant;

patient recruitment may be slower than expected; and

patients may drop out of the trials.

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.

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

Our strategy for developing and commercializing our products is dependent upon maintaining our current arrangements and establishing new arrangements with research collaborators, corporate collaborators and others. We have active collaboration agreements with GlaxoSmithKline and Dainippon Sumitomo Pharma Co. Ltd. and previously have had collaborations with Pfizer, Wyeth, Johnson & Johnson, 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.

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

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 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, 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;

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. However, 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 pending securities class action litigation could divert management s attention and harm our business.

The market price of our common stock declined significantly following our May 16, 2006 announcement of the FDA s action letters with respect to indiplon. In June 2007, two class action lawsuits (which have since been consolidated) were filed alleging, among other things, that we and certain of our officers and directors violated federal securities laws by making allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of indiplon in the 15mg dosage unit. Also in June 2007, a shareholder derivative

lawsuit was filed alleging, among other things, that certain of our current and former officers and directors breached their fiduciary duties by directing us to make allegedly false statements about such matters. In

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January 2008, we and the individual officers and directors filed a motion to dismiss the consolidated class action lawsuit. The shareholder derivative lawsuit has been stayed pending resolution of the motion to dismiss the federal class action lawsuit. We cannot currently predict the outcome of this litigation, which may be expensive and divert our management s attention and resources from operating the business. Additionally, we may not be successful in having such litigation dismissed or settled within the limits of our insurance.

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

As a result of the uncertainty in the future development of indiplon capsules and tablets, we have initiated restructuring activities in an effort to reduce operating costs, including a work force reduction announced in December 2007. 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. Any additional restructuring efforts could divert the attention of our management away from our operations, harm our reputation and increase our expenses. 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.

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.

Based on the results of preclinical studies and Phase I, Phase II and Phase III clinical trials on indiplon, as well as a non-clinical data package related to indiplon manufacturing, formulation and commercial product development, we assembled and filed with the FDA New Drug Applications (NDAs) for both indiplon capsules and indiplon tablets. On May 15, 2006, we received two complete responses from the FDA regarding our indiplon capsule and tablet NDAs. These responses indicated that indiplon 5mg and 10mg capsules were approvable (2006 FDA Approvable Letter) and that the 15mg tablets were not approvable (FDA Not Approvable Letter).

On June 12, 2007, we resubmitted our NDA for indiplon 5mg and 10mg capsules seeking clearance to market indiplon capsules for the treatment of insomnia. The FDA accepted the NDA resubmission and established a Prescription Drug User Fee Act (PDUFA) date of December 12, 2007. On December 12, 2007 we received an action letter from the FDA stating the indiplon 5mg and 10mg capsules are approvable (2007 FDA Approvable Letter). The 2007 FDA Approvable Letter acknowledged that the resubmitted NDA had addressed the issues raised in the 2006 FDA 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. We have requested and have been granted a formal meeting with the FDA, during the second quarter of 2008, to discuss the 2007 FDA Approvable Letter. 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.

The process of preparing and resubmitting the NDAs for indiplon capsules and tablets will require significant resources and could be time consuming and subject to unanticipated delays and cost. As a result of the 2006 FDA Approvable Letter, 2007 FDA Approvable Letter and FDA Not Approvable Letter, there is a significant amount of uncertainty regarding the future development of indiplon capsules and tablets. Should the NDAs be refiled, the FDA could again refuse to approve one or both NDAs, 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 NDAs are 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 also 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. 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 one or both NDAs, or the FDA refuses to accept or approve the resubmitted NDAs for any reason or we experience a further delay in approval and subsequent commercialization of indiplon, our business and reputation would be harmed and our stock price would decline.

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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 $207.3 million and $107.2 million for the years ended December 31, 2007 and 2006, respectively. As a result of ongoing operating losses, we had an accumulated deficit of $614.7 million and $407.4 million as of December 31, 2007 and 2006, respectively. We do not expect to be profitable for the year ended December 31, 2008.

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.

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. 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 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 GnRH 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.

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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, or 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 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:

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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 corresponding state 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.

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;

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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 new or changed 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 new or changed 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 $4 per share to approximately $14 per share. The market price of our common stock may fluctuate in response to many factors, including:

developments related to the FDA approval process for indiplon;

the results of our clinical trials;

developments concerning our strategic alliance agreements;

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

developments in patent or other proprietary rights;

future sales of our common stock by existing stockholders;

comments by securities analysts;

general market conditions;

fluctuations in our operating results;

government regulation;

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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, 2008, our short-term investments included $22.6 million of high-grade (AAA rated) auction rate securities issued by student loan providers. 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, the auction rate market reestablishes itself, another secondary market evolves for these securities, or to maturity. 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, until a future auction on these investments is successful, the securities are redeemed by the issuer or they mature. As of March 31, 2008, the carrying value of all auction rate securities was reduced by $1.0 million, from $22.6 million to $21.6 million, reflecting an estimated change in fair market value due solely to a lack of liquidity. Although the auction rate securities continue to pay interest according to their stated terms, based on valuation models, we recorded an unrealized loss of approximately $1.0 million in accumulated other comprehensive loss as a reduction in shareholders equity. 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.

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.

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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, irritable bowel syndrome, anxiety, depression, pain, diabetes, 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;

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.

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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, 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.

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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)

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 1, 2008

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