NEUROCRINE BIOSCIENCES INC
Form 10-Q
August 03, 2007

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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 June 30, 2007

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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer þ Non-accelerated filer o

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, 37,989,852 as of July 27, 2007.

NEUROCRINE BIOSCIENCES, INC.
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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)

	June 30, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,485	$ 80,981
Short-term investments, available-for-sale	95,812	101,623
Receivables under collaborative agreements	35	7,191
Other current assets	3,263	3,863
Total current assets	150,595	193,658
Property and equipment, net	86,524	91,378
Restricted cash	5,250	5,250
Prepaid royalty	94,000	94,000
Other non-current assets	5,495	5,391
Total assets	$ 341,864	$ 389,677
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 15,663	$ 15,627
Deferred revenues	9	
Current portion of long-term debt	3,271	4,489
Total current liabilities	18,943	20,116
Long-term debt	47,933	49,152
Other liabilities	5,939	5,693
Total liabilities	72,815	74,961
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 37,989,852 as of June 30, 2007 and 37,905,988 as of December 31, 2006	38	38
Additional paid-in capital	727,812	721,930
Accumulated other comprehensive income	634	99

Accumulated deficit	(459,435)	(407,351)
Total stockholders equity	269,049	314,716
Total liabilities and stockholders equity	$ 341,864	$ 389,677

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 June 30,		Six Months Ended June 30,	
	2007	**2006**	**2007**	**2006**
Revenues:				
Sponsored research and development	$ 21	$ 277	$ 107	$ 6,155
License fees and milestones		727		6,085
Sales force allowance		8,240		16,480
Grant revenue	27		45	
	-		-	
Total revenues	48	9,244	152	28,720
Operating expenses:				
Research and development	18,789	26,112	37,850	53,847
Sales, general and administrative	8,807	12,396	17,124	31,731
Total operating expenses	27,596	38,508	54,974	85,578
Loss from operations	(27,548)	(29,264)	(54,822)	(56,858)
Other income and (expense):				
Interest income and other income	2,032	2,758	4,456	5,420
Interest expense	(848)	(943)	(1,718)	(1,912)
Total other income, net	1,184	1,815	2,738	3,508
Net loss	$(26,364)	$(27,449)	$(52,084)	$(53,350)
Net loss per common share:				
Basic and diluted	$ (0.69)	$ (0.73)	$ (1.37)	$ (1.42)
Shares used in the calculation of net loss per common share:				
Basic and diluted	37,969	37,764	37,938	37,560

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)

	Six Months Ended June 30,	
	2007	**2006**
CASH FLOW FROM OPERATING ACTIVITIES		
Net loss	$ (52,084)	$ (53,350)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,027	5,356
Deferred revenues	9	(5,084)
Loan forgiveness on notes receivable from stockholder		50
Share-based compensation expense	5,203	9,478
Change in operating assets and liabilities:		
Accounts receivable and other current assets	7,756	(66)
Other non-current assets	94	(713)
Accounts payable and accrued liabilities	36	(4,109)
Other non-current liabilities	352	(355)
Net cash used in operating activities	(33,607)	(48,793)
CASH FLOW FROM INVESTING ACTIVITIES		
Purchases of short-term investments	(48,647)	(62,838)
Sales/maturities of short-term investments	54,795	137,947
Purchases of property and equipment	(173)	(2,742)
Net cash provided by investing activities	5,975	72,367
CASH FLOW FROM FINANCING ACTIVITIES		
Issuance of common stock	573	15,599
Principal payments on debt	(2,437)	(2,953)
Net cash (used in) provided by financing activities	(1,864)	12,646
Net (decrease) increase in cash and cash equivalents	(29,496)	36,220
Cash and cash equivalents at beginning of the period	80,981	49,948
Cash and cash equivalents at end of the period	$ 51,485	$ 86,168

See accompanying notes to the condensed consolidated financial statements.

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

1. BASIS OF PRESENTATION

The condensed consolidated financial statements included herein are unaudited. These statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, these financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of the financial position, results of operations, and cash flows for the periods presented. The results of operations for the interim period shown in this report are not necessarily indicative of results expected for the full year. These financial statements should be read in conjunction with the Management s Discussion and Analysis of Financial Condition and Results of Operations, Quantitative and Qualitative Disclosures About Market Risk and the financial statements and notes thereto for the year ended December 31, 2006 and the three months ended March 31, 2007 included in our Annual Report on Form 10-K for the year ended December 31, 2006 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2007, respectively, 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 insomnia, anxiety, depression, endometriosis, irritable bowel syndrome, pain, diabetes and other neurological and endocrine-related diseases and disorders. The Company currently has ten programs in various stages of research and development, including six programs in clinical development. While the Company independently develops many of its own product candidates, Neurocrine is in a collaboration for one of its programs. The Company s lead clinical development program, indiplon, is a drug candidate for the treatment of insomnia.

On May 15, 2006, the Company received two complete responses from the Food and Drug Administration (FDA) regarding the indiplon capsule and tablet New Drug Applications (NDAs). These responses indicated that indiplon 5 mg and 10 mg capsules were approvable (FDA Approvable Letter) and that the 15 mg tablets were not approvable (FDA Not Approvable Letter).

The FDA Not Approvable Letter requested that Neurocrine reanalyze certain safety and efficacy data and questioned the sufficiency of the objective sleep maintenance clinical data with the 15 mg tablet in view of the fact that the majority of the indiplon tablet studies were conducted with doses higher than 15 mg. Neurocrine held an end-of-review meeting with the FDA related to the FDA Not Approvable Letter in October 2006. This meeting was specifically focused on determining the actions needed to bring indiplon tablets from Not Approvable to Approval in the resubmission of the NDA for indiplon tablets. The FDA has requested additional long-term safety and efficacy data with the 15 mg dose for the adult population and the development of a separate dose for the elderly population. In discussions, Neurocrine and the FDA noted positive efficacy data for sleep maintenance with both indiplon capsules and tablets. On the basis of these discussions, the Company is formulating a strategy to pursue a sleep maintenance claim for indiplon. The evaluation of indiplon for sleep maintenance is ongoing and includes both indiplon capsules and tablets.

The FDA Approvable Letter requested that Neurocrine reanalyze data from certain preclinical and clinical studies to support approval of indiplon 5 mg and 10 mg capsules for sleep initiation and middle of the night dosing. The FDA Approvable Letter also requested reexamination of the safety analyses. The Company held an end-of-review meeting with the FDA related to the FDA Approvable Letter in August 2006. This meeting was specifically focused on determining the actions needed to bring indiplon capsules from Approvable to Approval in the resubmission of the NDA for indiplon capsules. At the meeting the FDA requested that the resubmission include further analyses and

modifications of analyses previously submitted to address questions raised by the FDA in the initial review. This reanalysis has been completed. The FDA also requested, and the Company has completed, a supplemental pharmacokinetic/food effect profile of indiplon capsules including several meal types. On June 12, 2007, the Company resubmitted its NDA for indiplon 5 mg and 10 mg capsules. The Company is currently awaiting a formal response from the FDA regarding the acceptance of this resubmission.

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On June 22, 2006, Pfizer Inc. and the Company agreed to terminate their collaboration and license agreements to develop and co-promote indiplon effective December 19, 2006. As a result, Neurocrine reacquired all worldwide rights for indiplon capsules and tablets and is responsible for any costs associated with development, registration, marketing and commercialization of indiplon.

3. IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS

During the first six months of 2007, the Company adopted the following accounting standard, which did not have a material effect on its consolidated results of operations or financial condition:

FASB Interpretation No. 48 (FIN 48), Accounting for Uncertainty in Income Taxes, an interpretation of FASB No. 109 . FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes , and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. See note 12.

4. SHARE-BASED COMPENSATION

The Company s net loss for the three and six months ended June 30, 2007 and 2006 includes $2.8 million and $2.7 million and $5.2 million and $9.5 million, respectively, of compensation expense related to the Company s share-based compensation awards. The compensation expense related to the Company s share-based compensation arrangements is recorded as components of sales, 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 June 30,		Six Months Ended June 30,	
	2007	**2006**	**2007**	**2006**
Sales, general and administrative	$1.5	$0.8	$2.8	$5.6
Research and development	1.3	1.8	2.4	3.9

Cash received from stock option exercises for the six months ended June 30, 2007 and 2006 was $0.6 million and $15.1 million, respectively. The Company issued approximately 76,000 shares of common stock related to stock option exercises during the six months ended June 30, 2007.

Stock Option Assumptions

The exercise price of all options granted during the six months ended June 30, 2007 and 2006 was equal to the market value 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 and six months ended June 30, 2007 and 2006:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	**2006**	**2007**	**2006**
Risk-free interest rate	4.97%	5.1%	4.82%	4.59%
Expected volatility of common stock	62.91%	64.51%	65.36%	43.64%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected option term	4.75 years	4.75 years	4.75 years	4.75 years

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.

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6. 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.

7. 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.

The Company carries as a long-lived asset on its balance sheet, a prepaid royalty arising from its acquisition in February 2004 of Wyeth s financial interest in indiplon. The Company s current and historical operating and cash flow losses and the action letters on indiplon from the FDA are indicators of impairment for the prepaid royalty. However, the Company believes the future cash flows to be realized from the prepaid royalty will exceed the asset s carrying value. The Company intends to pursue approvals of indiplon for both sleep onset and maintenance and to seek a commercialization partner. Accordingly, the Company has not recognized any impairment losses through June 30, 2007. However, events both within and outside of the Company s control, such as competition from other insomnia therapeutic agents, disease prevalence, further FDA actions related to indiplon, the Company s ability to partner indiplon, insomnia market dynamics and general market conditions may have an impact on the Company s ability to recover the carrying value of this asset in the future.

8. 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 1.8 million and 0.8 million for the three months ended June 30, 2007 and 2006, respectively and 1.6 million and 1.5 million for the six months ended June 30, 2007 and 2006, respectively.

9. 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 June 30, 2007 and 2006, comprehensive loss was $26.1 million and $27.6 million, respectively. For the six months ended June 30, 2007 and 2006, comprehensive loss was $51.5 million and $53.2 million, respectively.

10. 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, sales force allowance and advance payments for sponsored research revenues received in excess of amounts earned are classified as deferred

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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. Revenue related to the sales force allowance is recognized based on the related costs incurred to operate the sales force.

11. 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 because it provides reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial. 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.

12. INCOME TAXES

On July 13, 2006, the FASB issued FIN 48. 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, 2006 and at June 30, 2007, and has not recognized interest and/or penalties in the statement of operations for the first six months of 2007.

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, 2007, the Company had net deferred tax assets of $210.6 million. The deferred tax assets are primarily composed of federal and state tax net operating loss carryforwards and federal and state R&D credit carryforwards. 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 Company s net deferred tax assets. Additionally, the future utilization of the Company s net operating loss and R&D credit carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of ownership changes that may have occurred previously or that could occur in the future. The Company has not yet determined whether such an ownership change has occurred, however, the Company plans to complete a Section 382/383 analysis regarding the limitation of the net operating losses and research and development credits. When this analysis is completed, the Company plans to update its unrecognized tax benefits under FIN 48. Therefore, the Company expects that the unrecognized tax benefits may change within 12 months of this reporting date. At this time, the Company cannot estimate how much the unrecognized tax benefits may change. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in the Company s unrecognized tax benefits will not impact

its effective tax rate.

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13. 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. The complaint 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 June 26, 2007, a second purported class action lawsuit with similar allegations was filed in the same court (Gopal Batra, Ph.D. v. Neurocrine Biosciences, Inc.).

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 behalf of the Company 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 the Company 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.

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 on the Company s future financial results, if any, is not subject to reasonable estimate as of June 30, 2007.

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, 2006 and the three months ended March 31, 2007 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K for the year ended December 31, 2006 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2007, respectively.

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 insomnia, anxiety, depression, endometriosis, irritable bowel syndrome, pain, diabetes and other neurological and endocrine-related diseases and disorders. We currently have ten programs in various stages of research and development, including six programs in clinical development. While we independently develop many of our product candidates, we are in a collaboration for one of our programs. Our lead clinical development program, indiplon, is a drug candidate for the treatment of insomnia.

On May 15, 2006, we received two complete responses from the Food and Drug Administration (FDA) regarding our indiplon capsule and tablet NDAs. These responses indicated that indiplon 5 mg and 10 mg capsules were approvable (FDA Approvable Letter) and that the 15 mg tablets were not approvable (FDA Not Approvable Letter).

The FDA Not Approvable Letter requested that we reanalyze certain safety and efficacy data and questioned the sufficiency of the objective sleep maintenance clinical data with the 15 mg tablet in view of the fact that the majority of our indiplon tablet studies were conducted with doses higher than 15 mg. We held an end-of-review meeting with the FDA related to the FDA Not Approvable Letter in October 2006. This meeting was specifically focused on determining the actions needed to bring indiplon tablets from Not Approvable to Approval in the resubmission of the NDA for indiplon tablets. The FDA has requested additional long-term safety and efficacy data with the 15 mg dose for the adult population and the development of a separate dose for the elderly population. In discussions, we and the FDA noted positive efficacy data for sleep maintenance with both indiplon capsules and tablets. On the basis

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of these discussions, we are formulating a strategy to pursue a sleep maintenance claim for indiplon. The evaluation of indiplon for sleep maintenance is ongoing and includes both indiplon capsules and tablets.

The FDA Approvable Letter requested that we reanalyze data from certain preclinical and clinical studies to support approval of indiplon 5 mg and 10 mg capsules for sleep initiation and middle of the night dosing. The FDA Approvable Letter also requested reexamination of the safety analyses. We held an end-of-review meeting with the FDA related to the FDA Approvable Letter in August 2006. This meeting was specifically focused on determining the actions needed to bring indiplon capsules from Approvable to Approval in the resubmission of the NDA for indiplon capsules. At the meeting, the FDA requested that the resubmission include further analyses and modifications of analyses previously submitted to address questions raised by the FDA in the initial review. This reanalysis has been completed. The FDA also requested, and we have completed, a supplemental pharmacokinetic/food effect profile of indiplon capsules including several meal types. On June 12, 2007, we resubmitted our NDA for indiplon 5 mg and 10 mg capsules. We are currently awaiting a formal response from the FDA regarding the acceptance of this resubmission.

On June 22, 2006, we and Pfizer Inc. (Pfizer) agreed to terminate our collaboration and license agreements to develop and co-promote indiplon effective December 19, 2006. As a result, we reacquired all worldwide rights for indiplon capsules and tablets and are responsible for any costs associated with the development, registration, marketing and commercialization of indiplon.

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:

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, sales force allowance 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 to form reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial. 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.

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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.

During the second quarter of 2006, we received two letters from the FDA related to our NDA submissions for indiplon. These letters indicated that indiplon capsules were approvable and that indiplon tablets were not approvable. Additionally, on June 22, 2006, we announced that we and Pfizer had agreed to terminate our collaboration and license agreements to develop and co-promote indiplon. These two events are indicators of potential impairment for our prepaid royalty, which is carried as a long-lived asset on our balance sheet. This prepaid royalty arose out of our acquisition, in February 2004, of Wyeth s financial interest in indiplon for approximately $95.0 million, consisting of $50.0 million in cash and $45.0 million in our common stock. This transaction decreased our overall royalty obligation on sales of indiplon from six percent to three and one-half percent. In accordance with SFAS 144 we performed an analysis of the undiscounted cash flows related to this prepaid royalty. Based on our current expectations with respect to FDA approval, commercialization and our plan to partner indiplon, we have determined that the carrying value of this asset is fully recoverable, and we have not recognized any impairment charge to date. However, events both within and outside of our control, such as competition from other insomnia therapeutic agents, disease prevalence, further FDA actions related to indiplon, our ability to partner indiplon, insomnia market dynamics and general market conditions may have an impact on our ability to recover the carrying value of this asset in the future. In the event that either the tablet or capsule or both formulations of indiplon are further delayed, are not eventually approved by the FDA or are approved by the FDA but not successfully commercialized, an impairment charge would likely occur. We will continue to monitor this long-lived asset on a quarterly basis.

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 to certain employees pursuant to Employment Commencement Nonstatutory Stock Option Agreements. We also grant certain employees stock bonuses and restricted stock units 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, which we adopted effective January 1, 2006. We elected to use the modified prospective application in adopting SFAS 123R and therefore have not restated results for prior periods. The valuation provisions of SFAS 123R apply to new awards and to awards that are outstanding on the adoption date and subsequently modified or cancelled. Our results of operations for the first six months of 2007 and 2006 were impacted by the recognition of non-cash expense related to the fair value of our share-based compensation awards. Share-based compensation expense recognized under SFAS 123R for the three months ended June 30, 2007 and 2006 was $2.8 million and $2.7 million, respectively. Share-based compensation expense recognized under SFAS 123R for the six months ended June 30, 2007 and 2006 was $5.2 million and $9.5 million, respectively.

Stock option awards and restricted stock units 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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RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2007 AND 2006

Revenues were approximately $0.1 million for the three months ended June 30, 2007 compared with $9.2 million for the same period last year. The decrease in revenues for the three months ended June 30, 2007, compared with the same period in 2006, is primarily from revenues recognized in 2006 under the terminated collaboration agreement with Pfizer. During the second quarter of 2006, we recognized $9.2 million of revenue under the Pfizer collaboration agreement, comprised of $0.3 million in the form of sponsored development funding, $0.7 million resulting from amortization of up-front license fees, and $8.2 million related to the sales force allowance for operating our sales force.

Research and development expenses decreased to $18.8 million for the second quarter of 2007 compared with $26.1 million for the respective period in 2006. The $7.3 million decrease in research and development expenses is primarily due to cost savings related to our restructuring in 2006 and lower external development costs. The decrease in research and development staff levels reduced personnel costs by $2.7 million, from $10.9 million in the second quarter of 2006 to $8.2 million in the second quarter of 2007. External development costs decreased to $4.4 million in the second quarter of 2007 compared to $7.9 million in the same period last year. We started a new valnoctamide stereoisomers development program during 2007, which resulted in $0.8 million in external development costs during the second quarter of 2007. External development costs related to our Urocortin 2 and sNRI programs decreased by $0.6 million and $0.7 million, respectively, in the second quarter of 2007 compared to the same period in 2006. We also incurred external development costs of $3.1 million in the second quarter of 2006 related to the subsequently cancelled APL and H1 programs. We currently have ten programs in various stages of research and development, including six programs in clinical development. Additionally, laboratory costs decreased by $1.8 million in the second quarter of 2007 compared to the same period in 2006, primarily due to lower headcount. We also recognized $0.9 million in expense during the quarter related to our in-license of valnoctamide from Yissum Research Development Company of the Hebrew University of Jerusalem.

Sales, general and administrative expenses decreased to $8.8 million for the second quarter of 2007 compared with $12.4 million during the same period last year. The $3.6 million decrease in expenses from 2006 to 2007 is primarily the result of cost savings related to the staff reductions in the third quarter of 2006.

Other income decreased to $1.2 million for the second quarter of 2007 from $1.8 million for the second quarter of 2006. The decrease resulted primarily from lower average cash and investment balances as a result of operating losses, offset partially by higher investment returns during the second quarter of 2007.

Net loss for the second quarter of 2007 was $26.4 million, or $(0.69) per share, compared to $27.4 million, or $(0.73) per share, for the same period in 2006. Revenues during the second quarter of 2007 decreased significantly compared to the same period in 2006 primarily due to the cancellation of our collaboration agreement with Pfizer in 2006. The decrease in revenues during the second quarter of 2007 was mitigated by cost savings from our severance program and other cost saving activities implemented during the third quarter of 2006.

SIX MONTHS ENDED JUNE 30, 2007 AND 2006

Revenues were $0.2 million for the six months ended June 30, 2007 compared with $28.7 million for the respective period last year. The decrease in revenues during the first six months of 2007, compared with the respective period in 2006, is primarily from revenues recognized in 2006 under the terminated collaboration agreement with Pfizer. During the first half of 2006, we recognized $27.7 million in revenue from Pfizer, comprised of $6.1 million in the form of sponsored development funding, $5.1 million resulting from amortization of up-front license fees, and $16.5 million related to the sales force allowance for operating our sales force. Additionally, under our collaboration agreement with GlaxoSmithKline, we recognized $1.0 million in revenue during the first six months of 2006 for successfully enrolling the first patient in a Phase II clinical trial for our CRF program.

Research and development expenses decreased to $37.9 million for the first half of 2007 compared with $53.8 million for the respective period in 2006. This decrease in research and development expenses is primarily due to cost savings related to our restructuring in the third quarter of 2006 and lower external development costs. The decrease in research and development staff levels reduced personnel costs by $6.9 million, from $23.6 million in the first half of 2006 to $16.7 million during the same period in 2007. External development costs decreased by $5.8

million to $9.4 million in the first half of 2007 compared to $15.2 million in the

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same period in 2006. Due to efforts expended in addressing the FDA action letters and resubmitting our NDA for capsules, external development costs for our indiplon clinical program increased to $1.8 million in the first half of 2007 compared to $0.4 million during the same period in 2006. We started a new valnoctamide stereoisomers development program during 2007, which resulted in $1.0 million in external development costs during the first half of 2007. External development costs related to our Urocortin 2 and sNRI programs decreased by $2.3 million and $1.0 million, respectively, in the first half of 2007 compared to the same period in 2006. External development costs related to our subsequently cancelled APL and H1 programs included expenses of $5.1 million during the first half of 2006. Additionally, laboratory costs decreased by $3.0 million in the first half of 2007 compared to the same period in 2006, primarily due to the staff reductions mentioned above.

Sales, general and administrative expenses decreased to $17.1 million for the six months ended June 30, 2007 compared with $31.7 million during the same period last year. The $14.6 million decrease in expenses from 2006 to 2007 resulted primarily from cost savings related to the staff reductions in the third quarter of 2006.

Other income decreased to $2.7 million for the first half of 2007 from $3.5 million during the first half of 2006. The decrease resulted primarily from lower average cash and investment balances as a result of operating losses, offset partially by higher investment returns.

Net loss for the first half of 2007 was $52.1 million, or $(1.37) per share, compared to $53.4 million, or $(1.42) per share, for the same period in 2006. Revenues during the first half of 2007 have decreased significantly compared to the same period in 2006 primarily due to the cancellation of our collaboration agreement with Pfizer in 2006. Cost savings from our severance program during the third quarter of 2006 and other cost saving activities have offset the loss of revenue under our former Pfizer collaboration during 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 six months ended June 30, 2007 and 2006.

We expect to incur operating losses for the foreseeable future because of the expenses we expect to incur related to indiplon as well as costs to progress other programs through our pipeline. Future profitability is dependent upon the approval of our NDAs for indiplon by the FDA and upon acceptance of indiplon by prescribers and consumers.

LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2007, our cash, cash equivalents, and short-term investments totaled $147.3 million compared with $182.6 million at December 31, 2006. The decrease in cash balances at June 30, 2007 resulted primarily from our net loss of $52.1 million, offset by reduction in accounts receivable of $7.2 million.

Net cash used in operating activities during the first half of 2007 was $33.6 million compared with $48.8 million during the same period last year. The decrease in operating cash used during 2007 is primarily due to our restructuring during the third quarter of 2006, which decreased our personnel costs by $18.7 million during the first half of 2007 compared to the same period in 2006. Additionally, our accounts receivable decreased by $7.2 million.

Net cash provided by investing activities during the first half of 2007 was $6.0 million compared to $72.4 million for the first half of 2006. 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. In addition, purchases of property and equipment decreased from $2.7 million during the first half of 2006 to $0.2 million during the same period in 2007. Capital equipment purchases for the full year 2007 are expected to be approximately $1.0 million.

Net cash used in financing activities during the first half of 2007 was $1.9 million compared to net cash provided by financing activities of $12.6 million for the respective period last year. This fluctuation resulted primarily from cash proceeds from the issuance of common stock upon exercise of options which totaled $15.1 million for the first half of 2006 compared to $0.6 million during the same period this year. We expect similar fluctuations to occur throughout the year, as the amount and frequency of stock-related transactions are dependent upon the market performance of our common stock.

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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, 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 intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. In addition, we have financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. However, additional equity or debt financing might not be available on reasonable terms, if at all, and any additional equity financings will be dilutive to our stockholders. 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 June 30, 2007, 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 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 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.

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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 a 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.

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. The complaint alleges, 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 15 mg dosage unit. On June 26, 2007, a second purported class action lawsuit with similar allegations was filed in the same court (Gopal Batra, Ph.D. v. Neurocrine Biosciences, Inc.).

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 15 mg dosage unit.

We intend 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 our future financial results is not subject to reasonable estimate as of June 30, 2007.

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, 2006, 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 near-term success is dependent on the success of our lead product candidate, indiplon, and we may not receive regulatory approvals for it or our other product candidates or approvals may be delayed.

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 5 mg and 10 mg capsules were approvable (FDA Approvable Letter) and that the 15 mg tablets were not approvable (FDA Not Approvable Letter).

The FDA Not Approvable Letter requested that we reanalyze certain safety and efficacy data and questioned the sufficiency of the objective sleep maintenance clinical data with the 15 mg tablet in view of the fact that the majority of our indiplon tablet studies were conducted with doses higher than 15 mg. We held an end-of-review meeting with the FDA related to the FDA Not Approvable Letter in October 2006. This meeting was specifically focused on determining the actions needed to bring indiplon tablets from Not Approvable to Approval in the resubmission of the NDA for indiplon tablets. The FDA has requested additional long-term safety and efficacy data with the 15 mg dose for the adult population and the development of a separate dose for the elderly population. In discussions, we and the FDA noted positive efficacy data for sleep maintenance with both indiplon capsules and tablets. On the basis of these discussions, we are formulating a strategy to pursue a sleep maintenance claim for indiplon. The evaluation of indiplon for sleep maintenance is ongoing and includes both indiplon capsules and tablets.

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If we are unable to conduct the clinical trials to support a sleep maintenance claim for indiplon or if these clinical trials do not demonstrate the safety and efficacy of indiplon for sleep maintenance, we may not be able to resubmit the NDA for this indication. If we do obtain positive results from these clinical trials, we would then refile the NDA for indiplon for sleep maintenance.

The FDA Approvable Letter requested that we reanalyze data from certain preclinical and clinical studies to support approval of indiplon 5 mg and 10 mg capsules for sleep initiation and middle of the night dosing. The FDA Approvable Letter also requested reexamination of the safety analyses. We held an end-of-review meeting with the FDA related to the FDA Approvable Letter in August 2006. This meeting was specifically focused on determining the actions needed to bring indiplon capsules from Approvable to Approval in the resubmission of the NDA for indiplon capsules. At the meeting the FDA requested that the resubmission include further analyses and modifications of analyses previously submitted to address questions raised by the FDA in the initial review. This reanalysis has been completed. The FDA also requested, and we have completed, a supplemental pharmacokinetic/food effect profile of indiplon capsules including several meal types. On June 12, 2007, we resubmitted our NDA for indiplon 5 mg and 10 mg capsules. We are currently awaiting a formal response from the FDA regarding the acceptance of this resubmission.

The process of preparing and resubmitting the NDA for indiplon tablets will require significant resources and could be time consuming and subject to unanticipated delays and cost. 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 could 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 are unable to refile our NDA for indiplon tablets, or the FDA refuses to accept or approve the resubmitted capsule or tablet NDAs for any reason, or we experience a significant delay in approval and subsequent commercialization of indiplon, our business and reputation would be harmed and our stock price would decline.

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

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, 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 intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. 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;

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the costs associated with litigation matters;

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. In addition, we have financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. However, additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

(*) Because of the termination of our collaboration with Pfizer to develop and co-promote indiplon, we must identify a new partner and enter into a collaboration agreement with them or develop, commercialize, market and sell indiplon by ourselves.

On June 22, 2006, we announced that we and Pfizer had agreed to terminate our collaboration and license agreements to develop and co-promote indiplon. Under the collaboration, Pfizer had agreed to:

fund substantially all third-party costs related to future indiplon development, manufacturing and commercialization activities;

fund a 200-person Neurocrine sales force that would initially promote Zoloft® and, upon approval of the indiplon NDAs, co-promote indiplon in the United States;

be responsible for obtaining all regulatory approvals outside of the United States and regulatory approvals in the United States after approval of the first indiplon NDA; and

be responsible for sales and marketing of indiplon worldwide.

As a result of termination of this collaboration, we reacquired all worldwide rights for indiplon capsules and tablets. We received reimbursement of certain indiplon expenses incurred or committed prior to the June 22, 2006 notice date as well as certain ongoing expenses through December 19, 2006, the effective date of termination. We are responsible for any costs associated with additional data or clinical trials that may be required related to the indiplon NDAs.

We will seek another partner or partners, at an appropriate time, to assist us in the worldwide development and commercialization of indiplon or develop, commercialize, market and sell indiplon by ourselves. We face competition in our search for partners with whom we may collaborate. As a result, we may not be successful in finding another collaboration partner on favorable terms, or at all, and any failure to obtain a new partner on favorable terms could adversely affect indiplon development, commercialization and future sales, which would harm our business. Identifying a new partner and entering into a collaboration agreement with them or developing the necessary infrastructure to commercialize, market and sell indiplon ourselves could cause delays in obtaining regulatory approvals and commercialization of indiplon, which would negatively impact our business. If we choose to commercialize, market and sell indiplon ourselves, we will be required to substantially increase our internal sales, distribution and marketing capabilities. The development of the infrastructure necessary to commercialize, market and sell indiplon will require substantial resources and may divert the attention of our management and key personnel and negatively impact our other product development efforts. Moreover, we may not be able to hire a sales force that is sufficient in size or has adequate expertise.

Pursuant to the collaboration agreement with Pfizer, our sales force ceased detailing Pfizer s antidepressant Zoloft® to psychiatrists as of June 30, 2006, the date of expiration of Zoloft® patent exclusivity. Pfizer notified us that as of July 1, 2006, Pfizer will no longer reimburse or support our sales force. Consequently, we terminated the entire sales force in July 2006 and incurred expenses of approximately $6.0 million in the third quarter of 2006 related to salary continuation, outplacement services, and other costs related to eliminating the sales force. We cannot assure you that we will be able to successfully rebuild the sales force in a timely manner, or at all, should indiplon be approved by the FDA.

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(*) 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 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 15 mg 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. 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.

Even if we ultimately receive an approval letter for indiplon or any other product, we may be unable to commercialize such products immediately upon receipt of such letter.

Commercialization of a product for which we have received an approval letter from the FDA could be delayed for a number of reasons, some of which are outside of our control, including delays in the FDA s issuance of approvals for our trademarks or delays in the completion of required procedures by agencies other than the FDA, such as the Drug Enforcement Administration (DEA). For example, one of our competitors received an approval letter from the FDA for its proprietary product. In connection with the approval, the FDA recommended that the competitor s product be classified as a Schedule IV controlled substance by the DEA. However, because the Federal government s administrative process for formally classifying the product as a Schedule IV controlled substance was not yet complete, the competitor s product launch was delayed several months. Indiplon, like the competitor s product, and like all non-benzodiazepine hypnotics, is expected to be a Schedule IV controlled substance requiring classification by the DEA. There can be no assurance that we will receive DEA scheduling promptly. If we receive an approval letter for indiplon and are unable to commercialize indiplon promptly thereafter, our business and financial position may be materially adversely affected due to reduced revenue from product sales during the period that commercialization is delayed. In addition, the exclusivity period, or the time during which the FDA will prevent generic pharmaceuticals from introducing a generic copy of the product, begins to run upon receipt of the approval letter from the FDA and, therefore, to the extent we are unable to commercialize a product upon receipt of an approval letter, our long-term product sales and revenues could be adversely affected.

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

Any failure or substantial delay in completing clinical trials for our product candidates may severely harm our business. 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 indiplon and our other product candidates, we face the risks that:

- the product may not prove to be effective;
- we may discover that a product candidate may cause harmful side effects;
- the results may not replicate the results of earlier, smaller trials;
- we or the FDA or similar foreign regulatory authorities may suspend the trials;
- the results may not be statistically significant;
- patient recruitment may be slower than expected; and
- patients may drop out of the trials.

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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.

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 $107.2 million and $22.2 million for the years ended December 31, 2006 and 2005, respectively. As a result of ongoing operating losses, we had an accumulated deficit of $407.4 million and $300.1 million as of December 31, 2006 and 2005, respectively. We do not expect to be profitable for the year ended December 31, 2007. Additionally, we will be responsible for any costs associated with additional data or clinical trials that may be required related to the indiplon NDAs.

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. High portions 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 depend on continuing our current collaboration 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 an active collaboration agreement with GlaxoSmithKline 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

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manufacturing and commercializing any resulting drugs.

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

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

failed to gain the requisite regulatory approvals of these products;

did not successfully commercialize products that we originate;

did not conduct its collaborative activities in a timely manner;

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

terminated its alliance with us;

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

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

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

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

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

We are dependent on licenses from third parties for some of our key technologies. These licenses typically subject us to various commercialization, reporting and other obligations. If we fail to comply with these obligations, we could lose important rights. For example, we have licensed indiplon from DOV Pharmaceutical, Inc. 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, Urocortin 2 which we license from Research Development Foundation, the Adenosine2A receptor antagonist we license from Almirall Prodesfarma, S.A., and valnoctamide and stereoisomers that we license from Yissum Research Development Company of the Hebrew University of Jerusalem. 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.

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;

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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.

Since indiplon is our most advanced product program, our business and reputation would be particularly harmed, and our stock price likely would be harmed, if we fail to receive necessary regulatory approvals on a timely basis or achieve market acceptance.

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:

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;

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- 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.

Potential future impairments under SFAS 144 could adversely affect our future results of operations and financial position.

In accordance with Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, we assess our long-lived assets for impairment quarterly or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. 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 the carrying amount is not recoverable, we measure the amount of any impairment by comparing the carrying value of the asset to the present value of the expected future cash flows (fair value) associated with the use of the asset. If the carrying amount of the asset were determined to be impaired, an impairment loss to write-down the carrying value of the asset to fair value would be required.

For example, our June 30, 2007 balance sheet reflects $94.0 million of prepaid royalties related to our acquisition in February 2004 of Wyeth s financial interest in indiplon for approximately $95.0 million, consisting of $50.0 million in cash and $45.0 million in our common stock. This transaction decreased our overall royalty obligation on sales of indiplon from six percent to three and one-half percent.

This transaction has been recorded as a long-term asset and will be amortized over the commercialization period of indiplon, based primarily upon indiplon sales. Given the FDA letters we received on our NDA submissions for indiplon and the subsequent cancellation of the collaboration agreement with Pfizer, we determined that indicators of potential impairment existed. We performed the undiscounted cash flow analysis and determined that the carrying value of the prepaid royalty was recoverable as of June 30, 2007. However, events both within and outside of our control, such as competition from other insomnia therapeutic agents, disease prevalence, further FDA actions related to indiplon, our ability to partner indiplon, insomnia market dynamics and general market conditions may have an impact on our ability to recover the carrying value of this asset in the future.

If we determine that the sum of the expected future undiscounted cash flows relating to this prepaid royalty is less than the carrying amount of the asset, the asset would be impaired, and we would be required to record a non-cash impairment loss to write-down the carrying value of the asset to fair value. A material reduction in earnings resulting from such a charge could cause us to fail to be profitable in the period in which the charge is taken or otherwise to fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

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.

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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;

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 and our independent registered public accounting firm s audit of that assessment 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.

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(*) 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 $8 per share to approximately $15 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;

developments related to litigation matters;

future sales of our common stock by existing stockholders;

comments by securities analysts;

general market conditions;

fluctuations in our operating results;

government regulation;

health care reimbursement;

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

public concern as to the safety of our drugs.

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, manufacturing 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, manufacturing, 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

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process may take many years to complete and may involve ongoing requirements for post-marketing studies. Any FDA or other regulatory approval of our product candidates, once obtained, may be withdrawn. If our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments.

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

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

Competition may also arise from, among other things:

other drug development technologies;

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

new small molecule or other classes of therapeutic agents.

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

We are performing research on or developing products for the treatment of several disorders including insomnia, anxiety, depression, endometriosis, irritable bowel syndrome, pain, Parkinson s Disease, and other neuro-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

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protection for our proprietary technology and compounds. However, we face the risk that we may not obtain any of these patents and that the breadth of claims we obtain, if any, may not provide adequate protection of our proprietary technology or compounds.

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

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

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

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

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

The use of any of our potential products in clinical trials, and the sale of any approved products, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of $10 million per occurrence and $10 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for product candidates in development, 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Incorporated by reference to Item 8.01 of our Current Report on Form 8-K filed on June 6, 2007.

ITEM 5. OTHER INFORMATION

On August 1, 2007, we entered into amended and restated employment agreements with Gary A. Lyons, our President and Chief Executive Officer and a member of our Board of Directors; Timothy P. Coughlin, our Vice President and Chief Financial Officer; Margaret E. Valeur-Jensen, Ph.D., our Executive Vice President, General Counsel and Secretary; Richard Ranieri, our Senior Vice President, Human Resources; and Kevin C. Gorman, Ph.D., our Executive Vice President and Chief Operating Officer. Copies of the amended and restated employment agreements are attached as Exhibits 10.1 through 10.5 to this Quarterly Report on Form 10-Q and are incorporated herein by reference.

On August 1, 2007, our Board of Directors approved the following Board compensation plan based upon a comparative market analysis. Directors who are not our employees or consultants will receive a $30,000 annual cash retainer and the Chairman of the Board will receive an annual cash retainer of $50,000. The Chairman of the Audit Committee will also receive a $19,000 annual cash retainer, the Chairman of the Compensation Committee will also receive a $12,000 annual cash retainer, and the Chairman of the Nominating/Corporate Governance Committee will also receive a $9,000 annual cash retainer. Additionally, each other member of the Audit Committee will receive an annual cash retainer of $12,000, each other member of the Compensation Committee will receive an annual cash retainer of $7,000, and each other member of the Nominating/Corporate Governance Committee will receive an annual cash retainer of $5,000. Additionally, all directors who are not our employees or consultants will receive $2,000 for each regular meeting of the Board of Directors.

Each non-employee director will receive a grant of a nonstatutory option to purchase 15,000 shares of our common stock (or 20,000 shares in the case of the Chairman of the Board) at each Annual Meeting of Stockholders, provided that such non-employee director has been a non-employee director for at least six months prior to the date of such Annual Meeting. Each new non-employee director will automatically be granted a nonstatutory stock option to purchase 30,000 shares of our common stock upon the date such person joins the Board of Directors. All options granted to non-employee directors vest monthly over the one-year period following the date of grant and have exercise prices equal to the fair market value of our common stock on the date of grant.

All of our non-employee directors will continue to be reimbursed for expenses incurred in connection with performing their duties as directors.

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)

10.1 Employment Agreement dated August 1, 2007 between the Company and Gary A. Lyons

10.2 Employment Agreement dated August 1, 2007 between the Company and Margaret E. Valeur-Jensen, Ph.D.

10.3 Employment Agreement dated August 1, 2007 between the Company and Kevin C. Gorman, Ph.D.

10.4 Employment Agreement dated August 1, 2007 between the Company and Richard Ranieri

10.5 Employment Agreement dated August 1, 2007 between the Company and Timothy P. Coughlin

10.6 Neurocrine Biosciences, Inc. 2003 Incentive Stock Plan, as amended and form of stock option agreement and restricted stock unit agreement

10.7 Neurocrine Biosciences, Inc. Nonqualified Deferred Compensation Plan, as amended

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

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(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: August 2, 2007

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