

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2004

OR

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 0-28150

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation or organization)

33-0525145

(IRS Employer Identification No.)

**12790 EL CAMINO REAL
SAN DIEGO, CALIFORNIA 92130**
(Address of principal executive offices)

(858) 617-7600

(Registrant's telephone number, including area code)

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 No

Indicate by checkmark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act): Yes No

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 36,465,181 as of October 27, 2004.

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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)

	September 30, 2004	December 31, 2003
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 84,694	\$ 105,854
Short-term investments, available-for-sale	239,653	347,314
Receivables under collaborative agreements	7,493	13,659
Other current assets	4,818	4,982
Total current assets	336,658	471,809
Property and equipment, net	98,985	56,236
Prepaid royalties	95,000	—
Deposits and restricted cash	18,244	25,539
Other non-current assets	3,732	1,371
Total assets	<u>\$ 552,619</u>	<u>\$ 554,955</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 29,573	\$ 56,386
Deferred revenues	37,787	49,666
Current portion of long-term debt	4,752	3,960
Total current liabilities	72,112	110,012
Long-term debt, net of current portion	63,946	32,473
Deferred revenues	—	18,241
Other liabilities	3,997	3,109
Total liabilities	140,055	163,835
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized; issued and outstanding shares were 36,458,313 as of September 30, 2004 and 35,311,893 as of December 31, 2003	36	35
Additional paid-in capital	671,543	622,526
Deferred compensation	(424)	(784)
Notes receivable from stockholders	(139)	(139)
Accumulated other comprehensive (loss) income	(1,112)	1,664
Accumulated deficit	(257,340)	(232,182)
Total stockholders' equity	412,564	391,120
Total liabilities and stockholders' equity	<u>\$ 552,619</u>	<u>\$ 554,955</u>

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except loss per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(unaudited)		(unaudited)	
Revenues:				
Sponsored research and development	\$ 8,605	\$ 17,580	\$ 16,480	\$ 81,651
License fees and milestones	26,096	11,319	49,803	29,306
Grant income	—	360	408	986
Total revenues	34,701	29,259	66,691	111,943
Operating expenses:				
Research and development	32,305	37,537	81,662	138,184
General and administrative	5,427	5,296	16,179	15,175
Total operating expenses	37,732	42,833	97,841	153,359
Loss from operations	(3,031)	(13,574)	(31,150)	(41,416)
Other income and (expenses):				
Interest income	2,102	3,724	6,899	8,518
Interest expense	(722)	—	(907)	(518)
Other income, net	2	19	1	123
Total other income, net	1,382	3,743	5,993	8,123
Loss before income taxes	(1,649)	(9,831)	(25,157)	(33,293)
Income taxes	(2)	3	1	156
Net loss	<u>\$ (1,647)</u>	<u>\$ (9,834)</u>	<u>\$ (25,158)</u>	<u>\$ (33,449)</u>
Net loss per common share:				
Basic and diluted	\$ (0.05)	\$ (0.31)	\$ (0.70)	\$ (1.07)
Shares used in the calculation of net loss per common share:				
Basic and diluted	36,427	32,053	36,108	31,397

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Nine Months Ended September 30,	
	2004	2003
	(unaudited)	
CASH FLOW FROM OPERATING ACTIVITIES		
Net loss	\$ (25,158)	\$ (33,449)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	4,803	2,893
Deferred revenues	(30,120)	74,069
Deferred expenses	3	(956)
Loan forgiveness on notes receivable	130	—
Non-cash compensation expenses	414	662
Change in operating assets and liabilities:		
Accounts receivable and other current assets	6,330	(17,961)
Restricted cash and other non-current assets	(1,409)	(24,733)
Accounts payable and accrued liabilities	(26,813)	36,236
Other non-current liabilities	888	2,009
Net cash (used in) provided by operating activities	(70,932)	38,770
CASH FLOW FROM INVESTING ACTIVITIES		
Purchases of short-term investments	(536,512)	(362,439)
Sales/maturities of short-term investments	639,109	242,908
Deposits	7,295	(3,000)
Purchase of royalty stream	(50,000)	—
Purchases of property and equipment	(47,552)	(33,003)
Net cash provided by (used in) investing activities	12,340	(155,534)
CASH FLOW FROM FINANCING ACTIVITIES		
Issuance of common stock	5,167	195,731
Proceeds received from issuance of debt	35,486	16,747
Principal payments on debt	(3,221)	(16,207)
Net cash provided by financing activities	37,432	196,271
Net (decrease) increase in cash and cash equivalents	(21,160)	79,507
Cash and cash equivalents at beginning of the period	105,854	44,313
Cash and cash equivalents at end of the period	\$ 84,694	\$ 123,820
Supplemental information:		
Increase in stockholder's equity and prepaid royalties from issuance of common stock	\$ 45,000	\$ —
Increase in property and related debt resulting from increasing ownership percentage in Science Park Center LLC	\$ —	\$ 14,076

See accompanying notes to the condensed consolidated financial statements.

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. The financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2003 included in our Annual Report on Form 10-K filed with the SEC.

In May 2003, Neurocrine Biosciences, Inc. (Neurocrine) increased its ownership interest in Science Park Center, LLC (Science Park) from 1% to 50.5% effective April 1, 2003. In May 2004, Neurocrine purchased the remaining 49.5% interest in Science Park. Accordingly, the financial statements of Science Park are included in the condensed consolidated financial statements as of September 30, 2004 and December 31, 2003 and for the three and nine months ended September 30, 2004 and 2003.

These financial statements should be read in conjunction with the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Quantitative and Qualitative Disclosures about Market Risk" contained herein and the audited financial statements and notes thereto for the year ended December 31, 2003 included in our Annual Report on Form 10-K filed with the SEC.

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

2. STOCKHOLDER'S EQUITY

The Company applies the intrinsic-value-based method prescribed in Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," in accounting for employee stock options. Accordingly, compensation expense is generally recognized only when options are granted with a discounted exercise price. Any resulting compensation expense is recognized ratably over the associated service period, which is generally the option vesting term.

The Financial Accounting Standards Board (FASB) is expected to issue in the fourth quarter of 2004 FASB Statement 123R, *Share-Based Payment* (FAS 123R). If adopted as currently contemplated, FAS 123R would require all companies to measure compensation cost for all share-based payments (including employee stock options) at fair value and recognize such costs in the statement of operations. FAS 123R would be effective for public companies for periods beginning after June 15, 2005. Management is currently evaluating the impact of FAS 123R, and monitoring the progress of the FASB related to FAS 123R.

The Company has determined pro forma net loss and related per share information as if the fair value method described in Statement of Financial Accounting Standard (SFAS) No. 123, "Accounting for Stock Based Compensation," had been applied to its employee stock-based compensation. The pro forma effect on net loss and net loss per share is as follows for the three and nine months ended September 30, 2004 and 2003 (in thousands, except for loss per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net loss:				
As reported	\$(1,647)	\$ (9,834)	\$(25,158)	\$(33,449)
Stock option expense	(6,384)	(4,238)	(18,154)	(14,569)
Pro forma net loss	<u>\$(8,031)</u>	<u>\$(14,072)</u>	<u>\$(43,312)</u>	<u>\$(48,018)</u>
Loss per share as reported (basic and diluted)	\$ (0.05)	\$ (0.31)	\$ (0.70)	\$ (1.07)
Pro forma loss per share (basic and diluted)	\$ (0.22)	\$ (0.44)	\$ (1.20)	\$ (1.53)

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3. 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.

4. 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.

5. 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 impairment is indicated, the Company measures the amount of such impairment by comparing the carrying value of the asset to the estimated fair value of the asset, which is generally determined based on the present value of the expected future cash flows. While the Company's current and historical operating and cash flow losses are indicators of impairment, the Company believes the future cash flows to be received from the long-lived assets will exceed the assets' carrying value, and accordingly the Company has not recognized any impairment losses through September 30, 2004.

6. INCOME (LOSS) PER SHARE

The Company computes net income (loss) per share in accordance with SFAS No. 128, "Earnings Per Share." Under the provisions of SFAS No. 128, basic net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common and common equivalent shares outstanding during the period. Additionally, potentially dilutive securities, comprised of incremental common shares issuable upon the exercise of stock options and warrants, are excluded from diluted loss per share because of their anti-dilutive effect. Potentially dilutive securities totaled 1.8 million and 2.0 million for the three-month period ended September 30, 2004 and 2003, respectively, and 2.1 million and 2.0 million for the nine-month period ended September 30, 2004 and 2003, respectively.

7. COMPREHENSIVE INCOME (LOSS)

Comprehensive income (loss) is calculated in accordance with SFAS No. 130, "Comprehensive Income." SFAS No. 130 requires the disclosure of all components of comprehensive income (loss), including net income (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 and nine months ended September 30, 2004, comprehensive loss was \$0.5 million and \$27.9 million, respectively. For the three and nine months ended September 30, 2003, comprehensive loss was \$11.7 million and \$34.4 million, respectively.

8. REVENUE RECOGNITION

Revenue under collaborative research agreements and grants is 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. Up-front, nonrefundable payments for license fees 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. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events which require substantive effort. Revenues from government grants are recognized based on a percentage-of-completion basis as the related costs are incurred. The Company achieved development milestones totaling \$17.5 million and \$20.5 million, under their Pfizer collaboration agreement, for the three and nine months ending September 30, 2004, respectively.

9. RESEARCH AND DEVELOPMENT EXPENSES

Research and development (R&D) expenses are recognized as incurred and include related salaries, contractor fees, facilities costs, administrative expenses and allocations of certain other costs. All such costs are charged to R&D expenses 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, the Company funds R&D, conducted on our behalf, at other companies and research institutions under agreements, which are generally cancelable. The Company reviews and accrues clinical trials expense based on work performed. Accrued clinical costs are subject to revisions as trials progress to completion. Revisions to accruals are charged to expense in the period in which the facts that give rise to the revision become known.

10. REAL ESTATE TRANSACTIONS

During the third quarter of 2004, the Company completed construction of a new facility. Land acquisition and construction costs for this facility were financed through the net proceeds of the sale of the Company's previous headquarters and a construction loan for up to \$60.6 million through a commercial bank. As of September 30, 2004, approximately \$57 million was outstanding under the construction loan. The construction loan requires a guaranty deposit of \$17.5 million, which amount is included in deposits and restricted cash at September 30, 2004, to be maintained at the bank for the duration of the loan. Interest on the construction loan was payable monthly at the prime rate plus .75 percentage points. In accordance with SFAS No. 34, applicable interest cost was capitalized during the construction period.

On October 28, 2004 the existing construction loan was repaid and the guaranty deposit was released to the Company. The construction loan was replaced with a \$49.5 million loan secured by a first mortgage on the property. This new loan bears interest at a rate of 6.48% per annum, and is being amortized over on a period of 30 years, with a balloon payment due on the tenth anniversary of the loan.

During the first quarter of 2004, the Company acquired a parcel of land adjacent to the new headquarters site for approximately \$7.7 million to allow for future expansion.

11. PREPAID ROYALTIES

During the first quarter of 2004, the Company entered into several agreements with Wyeth and DOV pursuant to which the Company acquired Wyeth's financial interest in indiplon (the Company's lead clinical candidate for the treatment of insomnia) for \$95.0 million, consisting of \$50.0 million in cash and \$45.0 million in Neurocrine common stock based on a 15 day average stock price prior to the date of the agreement. Wyeth's financial interest in indiplon arises from a 1998 license agreement between Wyeth and DOV whereby Wyeth licensed the indiplon technology to DOV in exchange for milestone payments and royalties on future sales of indiplon. The Company subsequently licensed the indiplon technology from DOV in exchange for milestones (a portion of which is payable by DOV to Wyeth) and royalties (a portion of which is payable by DOV to Wyeth). The agreements among the Company, Wyeth and DOV provide that the Company will make milestone and royalty payments to DOV net of amounts that DOV would have been obligated to pay to Wyeth such that the Company will retain all milestone, royalty and other payments on indiplon commercialization that would have otherwise been payable to Wyeth. This decreases the Company's 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 the asset will be amortized over the commercialization period of indiplon, based upon indiplon sales.

12. NEW ACCOUNTING PRONOUNCEMENTS

In January 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51." FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. In December 2003, the FASB issued FIN 46R, a revision to FIN 46. FIN 46R provides a broad deferral of the latest date by which all public entities must apply FIN 46 to certain variable interest entities to the first reporting period ending after March 15, 2004. The adoption of FIN 46 or FIN 46R did not have a material impact upon the Company's financial position, cash flows or results of operations.

In March 2004, the Emerging Issues Task Force ("EITF") reached a consensus on Issue No. 03-1, "The Meaning of Other-Than-

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Temporary Impairment and Its Application to Certain Investments.” EITF 03-1 provides guidance on other-than-temporary impairment models for marketable debt and equity securities accounted for under SFAS No. 115, “Accounting for Certain Investments in Debt and Equity Securities.” The EITF developed a basic three-step model to evaluate whether an investment is other-than-temporarily impaired. The provisions of EITF 03-1 are effective for the Company’s third quarter of fiscal 2004 and will be applied prospectively to all current and future investments. Quantitative and qualitative disclosures for investments accounted for under SFAS No. 115 are effective for the Company’s fiscal year ending 2004. The adoption of EITF 03-1 did not have a material effect on the Company’s financial position, cash flows or results of operations.

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 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, 2003 and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2003.

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, various female and male health disorders, multiple sclerosis, diabetes and other neurological and endocrine related diseases and disorders. To date, we have not generated any revenues from the sale of products, and we do not expect to generate any revenues until the Food and Drug Administration approves a drug candidate. We submitted a New Drug Application (NDA) for the immediate release formulation of our lead drug candidate indiplon in October 2004, and plan to file an NDA for the modified release formulation of indiplon in November 2004. We have funded our operations primarily through private and public offerings of our common stock and payments received under research and development agreements. We are developing a number of products with corporate collaborators and will rely on existing and future collaborators to meet funding requirements. We expect to generate future net losses until one or more of our drug candidates receive regulatory approval from the FDA and are successfully commercialized. As of September 30, 2004, we have incurred a cumulative deficit of \$257.3 million.

CRITICAL ACCOUNTING POLICIES

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 (which affect research and development expense). 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 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. Up-front, nonrefundable payments for license fees and advance payments for sponsored research revenues received in excess of amounts earned are classified as deferred revenue and recognized as income over the contract or development period. Estimating the duration of the development period includes continual assessment of development stages and regulatory requirements. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events, which require substantive effort, and achievement of the milestone was not readily assured at the inception of the agreement. Revenues from government grants are recognized based on a percentage-of-completion basis as the related costs are incurred.

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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 at other companies and research institutions under agreements, which are generally cancelable. We review and accrue clinical trials expenses based on work performed, which relies on estimates of total hours and costs incurred based on patient enrollment, completion of studies and other events. We follow this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

The following table summarizes our primary sources of revenue:

	Three Months Ended September 30,	
	2004	2003
	(in thousands)	
Revenues under collaboration agreements:		
Pfizer	\$33,267	\$27,088
GlaxoSmithKline	1,434	1,811
Total revenue under collaboration agreements	34,701	28,899
Grant income	—	360
Total revenues	<u>\$34,701</u>	<u>\$29,259</u>

Revenues were \$34.7 million for the third quarter of 2004 compared to \$29.3 million for the respective period last year. The increase in revenues for the three months ended September 30, 2004, compared to the respective period in 2003, results primarily from changes in revenue recognized under our collaboration agreement with Pfizer, Inc (Pfizer). During the third quarter of 2004, we recognized \$7.3 million from Pfizer for sponsored development funding compared to \$16.1 million for the same period last year. The \$8.8 million decrease is due to the winding down of the Phase III clinical program for indiplon. During the third quarter of 2004, we also recognized \$26.0 million in amortization of up-front license fees and milestones compared to \$10.9 million for the same period last year. This increase is due to the achievement of \$17.5 million in milestones for the successful completion of Phase III studies for long-term administration and sleep maintenance of indiplon during the third quarter of 2004, offset by a decrease in license fee revenue due to the timing of license fee recognition. Under our agreement with GlaxoSmithKline (GSK), we recognized \$1.4 million in sponsored research revenue and license fees this quarter and \$1.8 million in sponsored research revenue and license fees for the same quarter last year. The sponsored research portion of our collaboration agreement with GSK is scheduled to end during the first quarter of 2005.

Research and development expenses decreased to \$32.3 million for the third quarter 2004 compared to \$37.5 million for the respective period in 2003. This \$5.2 million decrease in research and development expenses is primarily due to the winding down of our Phase III program for indiplon (for insomnia) which is near completion, offset by increased research and development expenses in other programs. External development costs incurred related to indiplon for the third quarter of 2004 were \$8.9 million compared to \$23.6 million for the same period last year. This decrease of \$14.7 million is due to the tapering of our indiplon development program as it nears completion. The decrease in indiplon spending was partially offset by a \$4.0 million increase in external development costs for our other clinical programs when comparing the third quarter of 2004 to 2003. Additionally, research and development personnel costs have increased by \$1.7 million, from \$6.8 million in the third quarter of 2003 to \$8.5 million in the third quarter of 2004. Laboratory costs have increased from \$3.1 million in the third quarter of 2003 to \$4.7 million in the third quarter of 2004. Scientific consulting and research collaboration costs for the third quarter have also increased by \$1.0 million from 2003 to 2004. The increase in personnel, laboratory costs, and consulting and research collaboration costs is related to the expansion of non-indiplon research and development activities. We currently have 13 programs in various stages of research and development, including eight programs in clinical development. We expect increases in non-indiplon related research and development expense in the future as we seek to continue to advance and build our product portfolio focused on neurological and endocrine-related diseases and disorders.

General and administrative expenses increased to \$5.4 million for the third quarter of 2004 compared with \$5.3 million during the

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same period last year. The increase in expenses from 2003 to 2004 resulted primarily from the addition of administrative personnel needed to support broader research and development activities and the implementation of our commercialization strategy.

Interest income decreased to \$2.1 million during the third quarter of 2004 compared to \$3.7 million for the same period last year. The decrease primarily resulted from lower realized gains on investments due to lower cash and investment balances.

Net loss for the third quarter of 2004 was \$1.6 million, or \$0.05 per share, compared to \$9.8 million, or \$0.31 per share, for the same period in 2003. The decrease in the net loss resulted primarily from revenue recognized from milestone achievements under the indiplon collaboration with Pfizer. Net losses are expected to continue this year as our programs continue to advance through the various stages of the research and clinical development process.

To date, our revenues have come from funded research and development, achievements of milestones under corporate collaborations, and licensing of product candidates. The nature, timing and amount of these revenues may fluctuate substantially from period to period, which would affect our quarterly revenues and earnings. Accordingly, results and earnings of one period are not predictive of future periods.

NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

The following table summarizes our primary sources of revenue:

	Nine Months Ended September 30,	
	2004	2003
	(in thousands)	
Revenues under collaboration agreements:		
Pfizer	\$60,783	\$104,346
GlaxoSmithKline	5,500	5,459
Taisho	—	1,144
Wyeth	—	8
Total revenue under collaboration agreements	66,283	110,957
Grant income	408	986
Total revenues	<u>\$66,691</u>	<u>\$111,943</u>

Revenues were \$66.7 million for the first nine months of 2004 compared to \$111.9 million for the respective period last year. The decrease in revenues for the nine months ended September 30, 2004, compared to the respective period in 2003, results primarily from decreases in revenue recognized under our collaboration agreement with Pfizer. During the first nine months of 2004 we recognized \$12.3 million from Pfizer for sponsored development funding compared to \$77.3 million for the same period last year. The \$65.0 million decrease is due to the winding down of the Phase III clinical program for indiplon. During the first nine months of 2004, we also recognized \$28.0 million from amortization of up-front license fees compared to \$27.0 million for the same period last year. This increase in license fee revenue is due to the timing of the license fee recognition which began in February 2003, upon approval of the collaboration agreement with Pfizer. We also recognized \$20.5 million in milestone payments during the first nine months of 2004 for the successful completion of Phase III studies for long-term administration and sleep maintenance of indiplon. Under our agreement with GlaxoSmithKline, we recognized \$5.0 million in sponsored research and license fees for the first nine months of 2004 and \$5.5 million for the respective period in 2003. We also recognized \$0.5 million in milestone revenue during 2004 under the GSK agreement for selection of a development candidate in our CRF research program. Revenues recognized under the Taisho agreement totaled \$1.1 million during the first nine months of 2003. This \$1.1 million decrease in Taisho revenue is due to the restructuring of our collaboration agreement whereby we reacquired the worldwide rights to our diabetes drug candidate.

Research and development expenses decreased to \$81.7 million for the first nine months of 2004 compared with \$138.2 million for the respective period in 2003. This \$56.5 million decrease in research and development expenses is primarily due to the winding down of our Phase III program for indiplon (for insomnia) which is near completion, offset by increased research and development expenses in other programs. External development costs incurred related to indiplon for the first nine months of 2004 were \$20.3 million compared to \$92.2 million for the same period last year. This decrease of \$71.9 million is due to the tapering of our indiplon program as it nears completion. The decrease in indiplon spending was partially offset by a \$5.0 million increase in external development costs for our other clinical programs when comparing the first nine months of 2004 to 2003. Additionally, personnel costs have increased by \$4.3 million, from \$20.1 million in the nine months of 2003 to \$24.4 million for the nine months ending September 30, 2004. Laboratory costs have increased from \$8.5 million in the first nine-months of 2003 to \$12.1 million in the first nine-months of 2004.

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The increase in personnel and laboratory costs is related to the expansion of non-indiplon research and development activities. We expect increases in non-indiplon related research and development expense in the future as we seek to continue to advance and build our product portfolio focused on neurological and endocrine-related diseases and disorders.

General and administrative expenses increased to \$16.2 million for the nine months ended September 30, 2004 compared with \$15.2 million during the same period last year. The increase in expenses from 2003 to 2004 resulted primarily from the addition of administrative personnel needed to support broader research and development activities and the implementation of our commercialization strategy and increased insurance costs.

Interest income decreased to \$6.9 million during the first nine months of 2004 compared to \$8.5 million for the same period last year. The decrease primarily resulted from lower realized gains on investments due to lower cash and investment balances.

Net loss for the first nine months of 2004 was \$25.2 million, or \$0.70 per share, compared to \$33.4 million, or \$1.07 per share, for the same period in 2003. The decrease in the net loss resulted primarily from revenue recognized for milestone achievements in the indiplon collaboration with Pfizer. Net losses are expected to continue this year as our programs continue to advance through the various stages of the research and clinical development process.

To date, our revenues have primarily come from funded research and achievements of milestones under corporate collaborations. The nature and amount of these revenues may fluctuate substantially from period to period, which would affect our quarterly revenues and earnings. Accordingly, results and earnings of one period are not predictive of future periods.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2004, our cash, cash equivalents, and short-term investments totaled \$324.3 million compared with \$453.2 million at December 31, 2003. The decrease in cash and investment balances from December 31, 2003 to September 30, 2004 resulted primarily from the cash payment to Wyeth of \$50.0 million for its portion of the indiplon royalty stream, a \$27.6 million reduction in payables related to clinical trials and our net loss of \$25.2 million.

Net cash (used in) provided by operating activities during the first nine months of 2004 was \$(70.9) million compared with \$38.8 million during the same period last year. This fluctuation resulted primarily from the receipt of the initial licensing payment from Pfizer for \$100.0 million in the first quarter of 2003.

Net cash provided by (used in) investing activities during the first nine months of 2004 was \$12.3 million compared to \$(155.5) million for the same period in 2003. This fluctuation resulted primarily from the cash payment of \$50.0 million to Wyeth in the first quarter of 2004 for its portion of the indiplon royalty stream. The increase in net cash provided by investing activities also resulted in part from timing differences in investment purchases, sales and maturities and the fluctuations in our portfolio mix between cash equivalents and short-term investment holdings. In particular, during the third quarter of 2003, a portion of the net cash proceeds from our common stock issuance were used to purchase investments. We expect similar fluctuations to continue in future periods. Purchases of property and equipment increased from \$33.0 million in the first nine-months of 2003 to \$47.6 million for the same period in 2004, primarily due to the construction of our new corporate facility. Capital equipment purchases for 2004 are expected to be approximately \$11.0 million and will be financed primarily through debt arrangements.

Net cash provided by financing activities during the first nine months of 2004 was \$37.4 million compared with net cash provided by financing activities of \$196.3 million for the respective period last year. This fluctuation resulted primarily from the issuance of 3.75 million shares of our common stock in September 2003 yielding net cash proceeds of \$187.4 million. During the first nine months of 2004, we also financed \$31.0 million through our construction loan for the construction of our new facility, compared to \$13.7 million for the same period last year. Cash proceeds from the issuance of common stock under option programs decreased by \$3.1 million in the current nine-month period compared to the same period last 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.

During the third quarter of 2004, we completed construction of a new facility. Land acquisition and construction costs for this facility were financed through the net proceeds of the sale of our previous headquarters and a construction loan through a commercial bank. As of September 30, 2004, approximately \$57 million was outstanding under the construction loan. The construction loan requires a guaranty deposit of \$17.5 million to be maintained at the bank for the duration of the loan. On October 28, 2004 the existing construction loan was repaid and the guaranty deposit was released to us. The construction loan was replaced with a \$49.5 million

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loan secured by a first mortgage on the property. This new loan bears interest at a rate of 6.48% per annum, and is being amortized over on a period of 30 years, with a balloon payment due on the tenth anniversary of the loan.

During the first quarter of 2004, we entered into several agreements with Wyeth and DOV Pharmaceutical, Inc. (“DOV”) pursuant to which, we acquired Wyeth’s financial interest in indiplon for approximately \$95 million, consisting of \$50 million in cash and \$45 million in our common stock. Wyeth’s financial interest in indiplon arises from a 1998 license agreement between Wyeth and DOV whereby Wyeth licensed the indiplon technology to DOV in exchange for milestone payments and royalties on future sales of indiplon. We subsequently licensed the indiplon technology from DOV in exchange for milestones (a portion of which is payable by DOV to Wyeth) and royalties (a portion of which is payable by DOV to Wyeth). The agreements among us, Wyeth and DOV provide that we will make milestone and royalty payments to DOV net of amounts that DOV would have been obligated to pay to Wyeth such that we will retain all milestone, royalty and other payments on indiplon commercialization that would have otherwise been payable to Wyeth. This decreases our overall royalty obligation on sales of indiplon from six percent to three and one-half percent. This transaction was recorded as a long-term asset, and the asset will be amortized over the commercialization period of indiplon, based upon indiplon sales.

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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, the cost of product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We may seek to access the public or private equity markets whenever conditions are favorable. We may also seek additional funding through strategic alliances and other financing mechanisms. Adequate funding may not be available on terms acceptable to us, if at all. 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.

We expect to experience negative cash flow for the near future as we fund our operating losses, in-licensing or acquisition opportunities, and capital expenditures. To the extent that we are unable to obtain third-party funding for such costs, we expect that increased expenses will result in increased losses from operations. We may not be successful in the development of our product candidates, and even if we are successful, any products marketed may not generate sufficient revenues to enable us to earn a profit.

CAUTION ON FORWARD-LOOKING STATEMENTS

Our business is subject to significant risks, including but not limited to, the risks inherent in our research and development activities, including the successful continuation of our strategic collaborations, the successful completion of clinical trials, the lengthy, expensive and uncertain process of seeking regulatory approvals, uncertainties associated both with the potential infringement of patents and other intellectual property rights of third parties, and with obtaining and enforcing our own patents and patent rights, uncertainties regarding government reforms and of product pricing and reimbursement levels, technological change and competition, manufacturing uncertainties and dependence on third parties. Even if our product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons. Such reasons include the possibilities that the product will be ineffective or unsafe during clinical trials, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by proprietary rights of third parties. For more information about the risks we face, see "Risk Factors" included in Part I of our Annual Report on Form 10-K filed with the SEC and the discussions set forth below under the caption "Risk Factors."

INVESTMENT AND 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 40 months. If a 10% change in interest rates were to have occurred on September 30, 2004, 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.

RISK FACTORS

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 the Company

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

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

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

Based on the results of the Phase III clinical trials on indiplon, we have assembled and filed with the FDA an NDA for the immediate release formulation (IR) and are currently assembling, and plan to file in November 2004, an NDA for the modified release formulation (MR).. We face the risk that we may not successfully complete and submit the indiplon MR NDA on our projected timeline including risk that the data necessary for filing may not be collected or compiled within our projected timeframe. If we are forced to delay our indiplon MR NDA or the FDA rejects either or both of our NDAs or finds them incomplete or insufficient, our business and reputation may be harmed and our stock price may decrease. In addition, even if our indiplon NDAs are approved, the labeling granted by the FDA may 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.

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. We are currently conducting Phase III clinical trials in our indiplon development program for insomnia. This is our most advanced clinical program and represents a significant portion of our total clinical development activities and expenditures. If the FDA determines that we have failed to demonstrate that indiplon is safe and efficacious for the targeted patient populations or if the FDA does not approve the proposed indiplon product labeling, our business and reputation would be harmed and our stock price would be negatively affected.

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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 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.

Also, 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 expect to rely on our collaboration with Pfizer for the funding of the completion of our indiplon clinical program and for commercialization of indiplon.

Pfizer has 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 will initially promote Zolofit® and, upon approval of the indiplon NDA, will 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.

While our agreement with Pfizer requires them to use commercially reasonable efforts in the development and commercialization of indiplon, we cannot control the amount and timing of resources Pfizer may devote to our collaboration following FDA approval in the United States nor can we control when Pfizer will seek regulatory approvals outside of the United States. In addition, if Pfizer's development activities in pursuing new indications and uses of indiplon are not successful or Pfizer's sales and marketing activities for indiplon are not effective, indiplon sales and our business may be harmed.

Pfizer may terminate the collaboration at any time upon 180-days written notice, subject to payment of specified amounts related to ongoing clinical development activities. If Pfizer elects to terminate the collaboration prior to FDA approval, we will be responsible for regulatory and commercialization expenses while we seek another partner to assist us in the worldwide development and commercialization of indiplon. This could cause delays in obtaining marketing approvals and sales, and negatively impact our business. If Pfizer elects to terminate the collaboration after receipt of FDA approval, we would be forced to fund the Neurocrine sales force and/or seek new marketing partners for indiplon. This could lead to loss of sales and negatively impact our business. In the event the collaboration is terminated by Pfizer, 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 and commercialization and our business.

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

Since our inception, we have incurred significant net losses, including net losses of \$25.2 million and \$30.3 million for the nine months ended September 30, 2004 and the year ended December 31, 2003, respectively. As a result of ongoing operating losses, we had an accumulated deficit of \$257.3 million and \$232.2 million as of September 30, 2004 and December 31, 2003, respectively. We were not profitable for the year ended December 31, 2003, and we do not expect to be profitable in 2004. We have not yet completed the development, including obtaining regulatory approvals, of any products and, consequently, have not generated revenues from the sale of products. Even if we succeed in developing and commercializing one or more of our drugs, we may not be profitable. We also expect to continue to incur significant operating and capital expenditures as we:

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

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

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

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our revenues are unpredictable and may fluctuate, among other reasons, due to our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing and contract research payments. A high proportion of our costs are fixed, 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 strategic alliances and developing additional strategic alliances to develop and commercialize our product candidates.

We depend upon our corporate collaborators to provide adequate funding for a number of our programs. Under these arrangements, our corporate collaborators are responsible for:

- selecting compounds for subsequent development as drug candidates;
- conducting preclinical studies and clinical trials and obtaining required regulatory approvals for these drug candidates; and
- manufacturing and commercializing any resulting drugs.

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 collaboration agreements with Pfizer, GlaxoSmithKline, Wyeth and Eli Lilly and Company. Because we rely heavily on our corporate collaborators, the development of our projects would be substantially delayed if our collaborators:

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

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- fail to gain the requisite regulatory approvals of these products;
- do not successfully commercialize products that we originate;
- do not conduct their collaborative activities in a timely manner;
- do not devote sufficient time and resources to our partnered programs or potential products;
- terminate their alliances with us;
- develop, either alone or with others, products that may compete with our products;
- dispute our respective allocations of rights to any products or technology developed during our collaborations; or
- merge with a third party that may wish to terminate the collaboration.

These issues and possible disagreements with our 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 filing of our NDAs 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. In addition, we license some of the core research tools used in our collaborations from third parties, including the CRF receptor we license from The Salk Institute and use in our CRF program collaboration with GlaxoSmithKline and the excitatory amino acid transporters we license from the Oregon Health Sciences University. Other in-licensed technologies, such as the GnRH receptor we license from Mount Sinai School of Medicine and melanocortin subtype 4 we license from the University of Michigan, will be important for future collaborations for our GnRH and melanocortin programs. If we were to default on our obligations under any of our product licenses, such as our license to indiplon, we could lose some or all of our rights to develop, market and sell the product. 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 or development and, while we have filed an NDA in October 2004 for our first drug candidate, indiplon (IR), and we expect indiplon to be commercially available in 2005, there is the possibility that it will not be commercially available during 2005, if at all. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

- be found ineffective or cause harmful side effects during preclinical studies or clinical trials;
- fail to receive necessary regulatory approvals on a timely basis or at all;
- be precluded from commercialization by proprietary rights of third parties;
- be difficult to manufacture on a large scale; or
- be uneconomical or fail to achieve market acceptance.

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

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We are currently conducting Phase III clinical trials for indiplon. Since this is our most advanced product program, our business and reputation would be particularly harmed, and our stock price likely would be harmed, if the product does not prove to be efficacious in these clinical trials or we fail to receive necessary regulatory approvals on a timely basis or achieve market acceptance.

We have no 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 no experience in marketing or selling pharmaceutical products. We are currently initiating marketing activities for indiplon by hiring staff with experience in pharmaceutical sales, marketing and distribution. We will rely on Pfizer to co-promote indiplon with us in the United States and rely exclusively on Pfizer to market indiplon outside of the United States.

We will also rely on Pfizer to provide distribution, customer service, order entry, shipping, billing, customer reimbursement assistance and managed care sales support related to indiplon. 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 will delay the approval of our FDA applications and our introductions 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 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 commercialize our products. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations. Our third-party manufacturers might not comply with FDA regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. Our reliance on contract manufacturers also exposes us to the following risks:

- contract manufacturers may encounter difficulties in achieving volume production, quality control and quality assurance, and also may experience shortages in qualified personnel. As a result, our contract manufacturers might not be able to meet our clinical schedules or adequately manufacture our products in commercial quantities when required;
- switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all;
- our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store or distribute our products;
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, 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; and

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- if our primary contract manufacturer should be unable to manufacture indiplon for any reason, or should fail to receive FDA approval or Drug Enforcement Agency approval, commercialization of indiplon could be delayed, which would delay indiplon sales and negatively impact our business.

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

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

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

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

As is commonplace in the biotechnology industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

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

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

- the timing of receipt of marketing approvals;
- 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 and effective, we may not recover our investment.

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

We may require additional funding to continue our research and product development programs, including preclinical testing and clinical trials of our product candidates, for operating expenses and to pursue regulatory approvals for product candidates. We also may require additional funding to establish manufacturing and marketing capabilities in the future. We believe that our existing capital resources, together with interest income, and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, these resources might be insufficient to conduct research and development programs as planned. If we cannot obtain adequate funds, we may be required to curtail significantly one or more of our research and development programs or obtain funds through additional arrangements with corporate collaborators or others that may require us to relinquish rights to some of our technologies or product candidates.

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

- continued scientific progress in our research and development programs;
- the magnitude of our research and development programs;
- progress with preclinical testing and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and pursuing patent applications and enforcing patent claims;
- competing technological and market developments;
- the establishment of additional strategic alliances;
- the cost of commercialization activities and arrangements, including manufacturing of our product candidates; and
- the cost of product in-licensing and any possible acquisitions.

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

While we believe that we currently have adequate internal control procedures in place, we are still exposed to potential risks from recent legislation requiring companies to evaluate controls under Section 404 of the Sarbanes-Oxley Act of 2002.

We are evaluating our internal controls systems in order to allow management to report on, and our Registered Independent Public Accounting Firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act. We continue to perform the system and process evaluation and testing required in an effort to comply with the management certification and auditor attestation requirements of Section 404. As a result, we are incurring additional expenses and a diversion of management's time. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations since there is no precedent available by which to measure compliance adequacy. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we might be subject to sanctions or investigation by regulatory authorities, such as the Securities and Exchange Commission. Any such action could adversely affect our financial results and the market price of our common stock.

The price of our common stock is volatile.

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Over the course of the last 12 months, the price of our common stock has ranged from approximately \$41 per share to approximately \$70 per share. The market price of our common stock may fluctuate in response to many factors, including:

- the results of our clinical trials;
- developments concerning our strategic alliance agreements;
- announcements of technological innovations or new therapeutic products by us or others;
- developments in patent or other proprietary rights;
- future sales of our common stock by existing stockholders;
- comments by securities analysts;
- general market conditions;

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- 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.

If any of the risks described in this “Risk Factors” section occurs, it could cause our stock price to fall dramatically and may expose us to class action securities lawsuits which, even if unsuccessful, would be costly to defend and a distraction to management.

Risks Related to Our Industry

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, various female and male disorders, multiple sclerosis, diabetes 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.

Any of these competitive factors could reduce demand for our products.

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

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

- obtain patent protection for our products;
- preserve our trade secrets;
- prevent third parties from infringing upon our proprietary rights; and
- operate without infringing upon the proprietary rights of others, both in the United States and internationally.

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

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by 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 ground that our patents do not cover its technology. Interference proceedings declared by the United States Patent and Trademark Office 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 collaboration partners with respect to technologies used in potential products. Any claims that might be brought against us relating to infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Furthermore, if a patent infringement suit were brought against us or our collaboration partners, we or our collaboration partners 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 collaboration partners 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 collaboration partners 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.

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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 reduce our cash reserves and force us to seek additional financing.

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 “Investment and Interest Rate Risk.”

ITEM 4. CONTROLS AND PROCEDURES

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

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 our 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.

In July 2004, we implemented an enterprise resource planning (ERP) system, designed to align and integrate our employees, processes and technology through software applications. Additionally, the new ERP system has been designed to allow the Company to retain the control and integrity of its information systems as it grows in the future. The ERP system includes enterprise financial reporting applications (general ledger, fixed assets, forecasting, purchasing, accounts payable) and human resources applications (benefits administration, recruiting, administration). We believe that throughout the implementation process, we have maintained internal accounting control systems that are adequate to provide reasonable assurance that assets are safeguarded from loss or unauthorized use, and which produce adequate records for preparation of financial information. There were no other significant changes in the Company’s internal controls over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Section 404 of the Sarbanes-Oxley Act requires company management to assess and report on the company’s internal controls. It also requires a company’s independent, outside auditors to issue an “attestation” to management’s assessment, as well as assess the proper design and function of internal controls. The Company is required to comply with this requirement for the first time as of December 31, 2004 and has substantially completed the documentation to comply with this standard and is now completing management’s testing of internal controls. We expect to comply with the reporting disclosure requirements of Section 404 by our year ending December 31, 2004.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On July 27, 2004, the Salk Institute filed a demand for arbitration with the American Arbitration Association seeking information and additional milestone payments from us arising out of a 1993 licenses agreement. The parties entered into an agreement on September 17, 2004, resolving the dispute. The resolution of the matter did not have a material effect on our business, financial condition, or results of operations.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(A) EXHIBITS.

- 3.1 Restated Certificate of Incorporation(1)
- 3.2 Bylaws(1)
- 3.3 Certificate of Amendment of Bylaws(1)
- 31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14 and15d-14 promulgated under the Securities Exchange Act of 1934.
- 31.2 Certification of Chief Financial Officer pursuant to Rules 13a-14 and15d-14 promulgated under the Securities Exchange Act of 1934.
- 32* Certifications of Chief Executive Officer and Chief Financial Officerpursuant 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)

* 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 Actof 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 suchfiling.

(B) REPORTS ON FORM 8-K.

None

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: November 5, 2004

/s/ Paul W. Hawran

Paul W. Hawran
Executive Vice President and Chief Financial Officer
(Duly authorized Officer and Principal Financial Officer)

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gary A. Lyons, President and Chief Executive Officer of Neurocrine Biosciences, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Neurocrine Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during this period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of the internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Dated: November 5, 2004

/s/ Gary A. Lyons

Gary A. Lyons
President and Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul W. Hawran, Executive Vice President and Chief Financial Officer of Neurocrine Biosciences, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Neurocrine Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during this period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of the internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Dated: November 5, 2004

/s/ Paul W. Hawran

Paul W. Hawran
Executive Vice President and
Chief Financial Officer

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

In connection with the Quarterly Report of Neurocrine Biosciences, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gary A. Lyons, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), of the Securities Exchange Act of 1934; and
- (2) That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 5, 2004

By: /s/ Gary A. Lyons

Name: Gary A. Lyons
Title: President and Chief
Executive Officer

In connection with the Quarterly Report of Neurocrine Biosciences, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul W. Hawran, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (3) The Report fully complies with the requirements of Section 13(a) or 15(d), of the Securities Exchange Act of 1934; and
- (4) That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 5, 2004

By: /s/ Paul W. Hawran

Name: Paul W. Hawran
Title: Executive Vice President and
Chief Financial Officer