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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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 March 31, 2005

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 0-22705

**NEUROCRINE BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

**33-0525145**  
(IRS Employer Identification No.)

**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 36,641,360 as of April 27, 2005.

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NEUROCRINE BIOSCIENCES, INC.  
FORM 10-Q INDEX

		<u>PAGE</u>
<b><u>PART I.</u></b>	<b><u>FINANCIAL INFORMATION</u></b>	
<a href="#">ITEM 1:</a>	<a href="#">Financial Statements</a>	3
	<a href="#">Condensed Consolidated Balance Sheets as of March 31, 2005 and December 31, 2004</a>	3
	<a href="#">Condensed Consolidated Statements of Operations for the three months ended March 31, 2005 and 2004</a>	4
	<a href="#">Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2005 and 2004</a>	5
	<a href="#">Notes to the Condensed Consolidated Financial Statements</a>	6
<a href="#">ITEM 2:</a>	<a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	9
<a href="#">ITEM 3:</a>	<a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	23
<a href="#">ITEM 4:</a>	<a href="#">Controls and Procedures</a>	23
<b><u>PART II.</u></b>	<b><u>OTHER INFORMATION</u></b>	
<a href="#">ITEM 5:</a>	<a href="#">Other information</a>	25
<a href="#">ITEM 6:</a>	<a href="#">Exhibits and Reports on Form 8-K</a>	25
	<a href="#">Signatures</a>	25
<a href="#">EXHIBIT 31.1</a>		
<a href="#">EXHIBIT 31.2</a>		
<a href="#">EXHIBIT 32</a>		

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

NEUROCRINE BIOSCIENCES, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(in thousands, except for share information)

	March 31, 2005 (unaudited)	December 31, 2004
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 44,570	\$ 61,027
Short-term investments, available-for-sale	226,337	240,102
Receivables under collaborative agreements	4,228	8,213
Other current assets	5,899	4,473
Total current assets	<u>281,034</u>	<u>313,815</u>
Property and equipment, net	101,238	102,166
Restricted cash	5,775	5,250
Prepaid royalty	94,000	94,000
Other non-current assets	4,321	3,986
Total assets	<u>\$ 486,368</u>	<u>\$ 519,217</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 18,733	\$ 25,237
Deferred revenues	21,991	27,674
Current portion of long-term debt	6,458	6,674
Total current liabilities	<u>47,182</u>	<u>59,585</u>
Long-term debt	57,950	59,452
Deferred revenues	2,000	2,000
Other liabilities	4,516	4,353
Total liabilities	<u>111,648</u>	<u>125,390</u>
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 36,641,360 as of March 31, 2005 and 36,532,767 as of December 31, 2004	37	37
Additional paid-in capital	674,925	674,034
Deferred compensation	(198)	(312)
Notes receivable from stockholders	(69)	(69)
Accumulated other comprehensive loss	(3,190)	(1,908)
Accumulated deficit	<u>(296,785)</u>	<u>(277,955)</u>
Total stockholders' equity	<u>374,720</u>	<u>393,827</u>
Total liabilities and stockholders' equity	<u>\$ 486,368</u>	<u>\$ 519,217</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	
	March 31,	
	2005	2004
	(unaudited)	
<b>Revenues:</b>		
Sponsored research and development	\$ 4,416	\$ 5,369
License fees and milestones	6,448	11,319
Sales allowance	1,000	—
Grant income	—	253
Total revenues	<u>11,864</u>	<u>16,941</u>
<b>Operating expenses:</b>		
Research and development	25,603	26,388
Sales, general and administrative	5,608	5,283
Total operating expenses	<u>31,211</u>	<u>31,671</u>
Loss from operations	(19,347)	(14,730)
<b>Interest income and (expense):</b>		
Interest income	1,601	2,353
Interest expense	(1,084)	—
Total other income	<u>517</u>	<u>2,353</u>
Loss before income tax expense	(18,830)	(12,377)
Income tax expense	—	3
Net loss	<u>\$ (18,830)</u>	<u>\$ (12,380)</u>
<b>Net loss per common share:</b>		
Basic and diluted	<u>\$ (0.51)</u>	<u>\$ (0.35)</u>
<b>Shares used in the calculation of net loss per common share:</b>		
Basic and diluted	<u>36,598</u>	<u>35,527</u>

See accompanying notes to the condensed consolidated financial statements.

## NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(in thousands)

	Three Months Ended	
	March 31,	
	2005	2004
	(unaudited)	
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (18,830)	\$ (12,380)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,442	1,243
Deferred revenues	(5,683)	(12,695)
Deferred expenses	—	164
Non-cash compensation expenses	209	132
Change in operating assets and liabilities:		
Accounts receivable and other current assets	2,559	8,724
Other non-current assets	(335)	1,726
Accounts payable and accrued liabilities	(6,504)	(11,406)
Other non-current liabilities	163	—
Net cash used in operating activities	(25,979)	(24,492)
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>		
Purchases of short-term investments	(20,550)	(290,864)
Sales/maturities of short-term investments	33,033	301,100
Purchase of royalty stream	—	(50,000)
Deposit and restricted cash	(525)	7,988
Purchases of property and equipment	(1,514)	(24,051)
Net cash provided by (used in) investing activities	10,444	(55,827)
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>		
Issuance of common stock	796	1,777
Proceeds from debt financing	—	11,701
Principal payments on long-term obligations	(1,718)	(1,004)
Net cash (used in) provided by financing activities	(922)	12,474
Net decrease in cash and cash equivalents	(16,457)	(67,845)
Cash and cash equivalents at beginning of the period	61,027	105,854
Cash and cash equivalents at end of the period	\$ 44,570	\$ 38,009

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 U.S. generally accepted accounting principles 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 U.S. generally accepted accounting principles 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, 2004 included in our Annual Report on Form 10-K filed with the SEC.

These financial statements should be read in conjunction with the "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Quantitative and Qualitative Disclosures About Market Risk" and the audited financial statements and notes thereto for the year ended December 31, 2004 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

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

*Stockholders' 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 awarded if the fair market value of the stock on the date of the option grant exceeds the exercise price of the options. Any resulting compensation expense is recognized ratably over the associated service period, which is generally the option vesting term.

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 Standards (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 months ended March 31, 2005 and 2004 (in thousands, except for loss per share data):

	Three Months Ended March 31,	
	2005	2004
Net loss:		
As reported	\$ (18,830)	\$ (12,380)
Stock option expense	(5,341)	(6,641)
Pro forma net loss	<u>\$ (24,171)</u>	<u>\$ (19,021)</u>
Net loss per share as reported (basic and diluted)	\$ (0.51)	\$ (0.35)
Pro forma net loss per share (basic and diluted)	\$ (0.66)	\$ (0.54)

The Financial Accounting Standards Board (FASB) issued SFAS No. 123R, *Share-Based Payment*, which requires 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. See discussion under Note 9 below.

## [Table of Contents](#)

### 2. USE OF ESTIMATES

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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.

### 3. 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.

### 4. 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 related 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 March 31, 2005.

### 5. LOSS PER COMMON SHARE

The Company computes net loss per share in accordance with SFAS No. 128, "Earnings Per Share." Under the provisions of SFAS No. 128, basic net loss per share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common and common equivalent shares outstanding during the period. Additionally, potentially dilutive securities, composed of incremental common shares issuable upon the exercise of stock options and warrants, are excluded from historical diluted loss per share because of their anti-dilutive effect. Potentially dilutive securities totaled 1.4 million and 2.4 million for the period ended March 31, 2005 and 2004, respectively.

### 6. COMPREHENSIVE LOSS

Comprehensive loss is calculated in accordance with SFAS No. 130, "Comprehensive Income." SFAS No. 130 requires the disclosure of all components of comprehensive loss, including net loss and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. The Company's components of comprehensive loss consist of the net loss and unrealized gains and losses on short-term investments. For the three months ended March 31, 2005 and 2004, comprehensive loss was \$20.1 million and \$12.0 million, respectively.

### 7. REVENUE RECOGNITION

Revenue under collaborative research and development agreements and grants is recognized as costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis and do not require scientific achievement as a performance obligation, and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. 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



## Table of Contents

substantive effort. Revenue related to the sales force allowance is recognized based on the incurrence of related costs associated with building and operating the sales function. Pfizer has agreed to pay for and support the creation of a 200-person Neurocrine sales force that will initially promote Pfizer's leading antidepressant drug, Zoloft<sup>®</sup>, to psychiatrists in the United States, and, upon approval of the indiplon NDA, will co-promote indiplon in the United States.

### 8. RESEARCH AND DEVELOPMENT EXPENSES

Research and development (R&D) expenses include related salaries, contractor fees, facilities costs, administrative expenses and allocations of certain other 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, 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 revision as trials progress to completion. Revisions to accruals are recorded in the period in which the facts that give rise to the revision become known.

### 9. NEW ACCOUNTING PRONOUNCEMENTS

In December 2004, the FASB issued SFAS No. 123R "Share Based Payment." This statement is a revision to SFAS No. 123 and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends FASB Statement No. 95, "Statement of Cash Flows." This statement requires a public entity to expense the cost of employee services received in exchange for an award of equity instruments. This statement also provides guidance on valuing and expensing these awards, as well as disclosure requirements of these equity arrangements. This statement was originally effective for the first interim reporting period that begins after June 15, 2005; however, a recent action by the Securities and Exchange Commission delayed the effective date until fiscal 2006.

SFAS No. 123R permits public companies to choose between the following two adoption methods:

1. A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date, or
2. A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using APB Opinion 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. The impact of the adoption of SFAS No. 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, valuation of employee stock options under SFAS No. 123R is similar to SFAS No. 123, with minor exceptions. For information about what the Company's reported results of operations and earnings per share would have been had it adopted SFAS No. 123, see the discussion under the heading "Stockholders' Equity" in Note 1 to the Company's Condensed Consolidated Financial Statements. The adoption of SFAS No. 123R's fair value method will have a significant impact on the Company's results of operations, although it will have no impact on its overall financial position. SFAS No. 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. The Company has not yet completed the analysis of the ultimate impact that this new pronouncement will have on the results of operations, nor the method of adoption for this new standard.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29." The amendments made by SFAS No. 153 are based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The amendment also eliminates the narrow

## [Table of Contents](#)

exception for nonmonetary exchanges of similar productive assets and replaces it with a broader exception for exchanges of nonmonetary assets that do not have commercial substance. The provisions of this SFAS No. 153 are effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The Company does not expect the adoption of SFAS No. 153 to have a material impact on its financial condition 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, 2004 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, 2004.*

#### 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 resubmitted a New Drug Application (NDA) for the immediate release (capsule) formulation of our lead drug candidate, indiplon (for insomnia), in April 2005, and plan to resubmit an NDA for the modified release (tablet) formulation of indiplon during the second quarter of 2005. 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 March 31, 2005, we have incurred a cumulative deficit of \$296.8 million and expect to incur operating losses in future periods.

#### 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 U.S. generally accepted accounting principles. 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 and development agreements, clinical trial accruals (which affect research and development expense), investments and fixed assets. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The items in our financial statements requiring significant estimates and judgments are as follows:

Revenues under collaborative research and development agreements are recognized as costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis and do not require scientific achievement as a performance obligation, and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. 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

## [Table of Contents](#)

scientific events, which require substantive effort, and achievement of the milestone was not readily assured at the inception of the agreement. Revenue related to the sales force allowance is recognized based on the incurrence of related costs associated with building and operating the sales function. Pfizer has agreed to pay for and support the creation of a 200-person Neurocrine sales force that will initially promote Pfizer's leading antidepressant drug, Zoloft<sup>®</sup>, to psychiatrists in the United States, and, upon approval of the indiplon NDA, will co-promote indiplon in the United States.

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 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 because 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 MARCH 31, 2005 AND 2004

The following table summarizes our primary sources of revenue:

	<u>Three Months</u>	
	<u>Ended March 31</u>	
	<u>2005</u>	<u>2004</u>
	<u>(in thousands)</u>	
Revenues under collaboration agreements:		
Pfizer	\$10,410	\$14,898
GlaxoSmithKline	1,454	1,790
Total revenue under collaboration agreements	11,864	16,688
Grant income	—	253
Total revenues	<u>\$11,864</u>	<u>\$16,941</u>

Revenues were \$11.9 million for the first quarter of 2005 compared with \$16.9 million for the respective period last year. The decrease in revenues for the three months ended March 31, 2005, compared with the respective period in 2004, results primarily from a decrease in revenues recognized under our collaboration agreement with Pfizer, Inc. (Pfizer). During the first quarter of 2005, we recognized \$10.4 million in revenue from Pfizer, \$4.0 million in the form of sponsored development funding, \$5.4 million resulting from amortization of up-front license fees, and \$1.0 million related to the sales force allowance received from Pfizer to commence the building of our sales force. During the first quarter of 2004, we recognized \$4.0 million from Pfizer in the form of sponsored development funding and an additional \$10.9 million resulting from amortization of up-front license fees. The decrease in revenue from the amortization of up-front license fees is due to the timing of the refiling of our New Drug Application for indiplon discussed above. Under the GlaxoSmithKline (GSK) agreement, we recognized \$1.4 million during the first quarter of 2005, which included a \$1.0 million milestone for successful completion of the research portion of our collaboration agreement. During the first quarter of 2004, we recognized \$1.8 million in revenue under the GSK collaboration.

Research and development expenses decreased to \$25.6 million for the first quarter 2005 compared with \$26.4 million for the respective period in 2004. This decrease in research and development expenses is primarily due to the wind down of our Phase III program for indiplon, which is nearing completion, offset by increased research and development expenses in other programs. External development costs incurred related to indiplon for the first quarter of 2005 were \$3.4 million compared to \$7.3 million for the same period last year. This decrease of \$3.9 million is due to the tapering of the indiplon program as it nears completion. External development costs for other programs have increased from \$4.7 million in the first quarter of 2004 to \$6.4 million in the first quarter of 2005. We currently have 12 programs in various stages of research and development, including eight programs in clinical development. Additionally, personnel costs have increased by \$1.1 million, from \$7.5 million in the first quarter of 2004 to \$8.6 million in the first quarter of 2005. The increase in personnel costs is related to the expansion of research and development activities. We expect increases in non-indiplon related research and development expenses to continue in the future as

## Table of Contents

we continue to advance and build our product portfolio focused on neurological and endocrine-related diseases and disorders.

Sales, general and administrative expenses increased to \$5.6 million for the first quarter of 2005 compared with \$5.3 million during the same period last year. The increase in expenses from 2004 to 2005 resulted primarily from the activities surrounding the implementation of our commercialization strategy, including commencing the building of our sales force.

Other income decreased to \$0.5 million during the first quarter of 2005 compared to \$2.4 million for the same period last year. The decrease primarily resulted from expensing of interest expense during the first quarter of 2005. While constructing the new headquarters during 2004, interest expense was capitalized in accordance with SFAS No. 34. Additionally, lower overall investment balances decreased the interest income recognized.

Net loss for the first quarter of 2005 was \$18.8 million, or \$0.51 per share, compared to \$12.4 million, or \$0.35 per share, for the same period in 2004. We expect to incur a net loss in 2005 as our research, development, pre-clinical studies and clinical trial activities continue. However, fluctuations in the quarterly results may occur due to the timing of milestone achievements related to our New Drug Application for indiplon under our collaboration agreement with Pfizer. Additionally, we will complete the build of our sales function during 2005, which will increase sales, general and administrative expenses. Because of the funding from Pfizer related to our sales function, revenue from sales force allowance will also increase during 2005.

To date, our revenues have come from funded research and development, achievements of milestones under corporate collaborations, and licensing of product candidates. The nature and amount of these revenues from period to period may lead to substantial fluctuations in the results of quarterly revenues and earnings. Accordingly, results and earnings of one period are not predictive of future periods. Collaborations accounted for 100% and 99% of our revenue for the quarters ended March 31, 2005 and 2004, respectively.

## LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2005, our cash, cash equivalents, and short-term investments totaled \$270.9 million compared with \$301.1 million at December 31, 2004. The decrease in cash balances at March 31, 2005 resulted primarily from our net loss of \$18.8 million and a decrease in accounts payable and accrued liabilities related to our declining clinical trial costs for indiplon.

Net cash used in operating activities during the first quarter of 2005 was \$26.0 million compared with \$24.5 million during the same period last year. This fluctuation resulted from the increase in our net loss from \$12.4 million in the first quarter of 2004 to \$18.8 million for the first quarter of 2005. Additionally, payments under accounts payable were \$11.4 million in the first quarter of 2004 compared to \$6.5 million in the first quarter of 2005.

Net cash provided by (used in) investing activities during the first quarter of 2005 was \$10.4 million compared to (\$55.8) million for the first quarter of 2004. This fluctuation resulted primarily from the prepayment of the Wyeth royalties on indiplon during the first quarter of 2004 for \$50.0 million. The fluctuation in net cash provided by (used in) investing activities also resulted, in part, from the timing differences in investment purchases, sales and maturities, and the fluctuation of our portfolio mix between cash equivalents and short-term investment holdings. In addition, purchases of property and equipment decreased from \$24.1 million in 2004 to \$1.5 million in 2005 as a result of the completion of construction of our new corporate headquarters in mid-2004. Capital equipment purchases for 2005 are expected to be approximately \$9.0 million. During the first quarter of 2005, we placed a deposit of \$525,000 with a local bank as security for a letter of credit. This letter of credit serves as security on our fleet of vehicles for the sales force.

Net cash (used in) provided by financing activities during the first quarter of 2005 was (\$0.9) million compared with net cash provided by financing activities of \$12.5 million for the respective period last year. This fluctuation resulted primarily from financing \$11.7 million through our construction loan in 2004. Cash proceeds from the issuance of common stock under option programs decreased by \$1.0 million in the current quarter compared to the same quarter 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.

## Table of Contents

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. We cannot assure you that adequate funding will 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 do not expect to be profitable from sales/royalties in 2005. We expect expenses to increase over the next several years as our sales, research, development, preclinical studies and clinical trial activities increase. To the extent that we are unable to obtain third-party funding for such expenses, or generate revenue from sales/royalties, we expect that increased expenses will result in increased losses from operations. We cannot assure you that we will be successful in the development of our product candidates, or that, if successful, any products marketed will generate sufficient revenues to enable us to earn a profit.

### 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."

### 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 March 31, 2005, 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 Relating 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, our recovery of prepaid royalties, and our liquidity and capital resources. All of our products are in research and development, and we have not yet received regulatory approval to commercialize any product from the FDA or any other regulatory body. In addition, we have limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain such approvals.

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

Based on the results of the Phase III clinical trials on indiplon, we assembled and filed with the FDA a New Drug Application (NDA) for both the immediate release capsule and the modified release tablet. The capsule NDA filing was not accepted by the FDA due to difficulties encountered in navigating the electronic NDA in the Common Technical Document (CTD) format. After reviewing the FDA's comments on the capsule NDA, we voluntarily withdrew the tablet NDA filing to address related navigational issues. The capsule and tablet NDAs share certain CTD modules and the decision to reformat both NDAs was made to ensure technical consistency between the NDAs. We met with the FDA to discuss our refiling plans and based on the FDA's input and discussions with our collaboration partner Pfizer, we refiled the capsule NDA on April 14, 2005 and plan to refile the tablet NDA during the second quarter of 2005. This timing has and will allow us to address navigational issues within the CTD format and allow us to update certain presentations consistent with our refiling plans. Filing of the tablet NDA in the second quarter will also allow us to incorporate Phase III data from an additional tablet study. We face the risk that we may not successfully reformat and resubmit the indiplon tablet NDA on our projected timeline. If we are forced to delay our indiplon tablet NDA resubmission for any reason or the FDA rejects either or both of our NDA resubmissions 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.

## Table of Contents

*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<sup>®</sup> 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 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.

Decisions within the collaboration are made within a series of joint committees comprised of Neurocrine and Pfizer representatives. In the event of disagreement at the committee level, the agreement provides for elevation of the issue to a joint steering committee and thereafter to senior executives at both companies. The agreement provides that certain decisions are Neurocrine decisions, certain decisions are Pfizer decisions and certain decisions require consensus among both parties before any action can be taken. We face the risk that decisions may be delayed as a result of this resolution process. Our agreement further provides that upon occurrence of certain events, some decisions designated as Neurocrine decisions may become Pfizer decisions.

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.

*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.



## Table of Contents

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 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 \$18.8 million and \$45.8 million for the three months ended March 31, 2005 and the year ended December 31, 2004, respectively. As a result of ongoing operating losses, we had an accumulated deficit of \$296.8 million and \$278.0 million as of March 31, 2005 and December 31, 2004, respectively. We were not profitable for the year ended December 31, 2004, and we do not expect to be profitable from product sales/royalties in 2005. 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 portion of our costs are predetermined on an annual basis, due in part to our significant research and development



## [Table of Contents](#)

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;
- 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 adenosine 2A receptor antagonist we license from Almirall Prodesfarma, S.A. Other in-licensed technologies, such as the GnRH

## Table of Contents

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 expect indiplon to be commercially available by 2006, there is the possibility that it will not be commercially available 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.

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

*We have 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 and marketing. 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

## Table of Contents

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
- 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.

## [Table of Contents](#)

*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.

*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;

## Table of Contents

- 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.

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

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

*The price of our common stock is volatile.*

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Over the course of the last 12 months, the price of our common stock has ranged from approximately \$34 per share to approximately \$65 per share. The market price of our common stock may fluctuate in response to many factors, including:

- developments related to the FDA approval process for indiplon;
- the results of our clinical trials;
- developments concerning our strategic alliance agreements;

## Table of Contents

- announcements of technological innovations or new therapeutic products by us or others;
- developments in patent or other proprietary rights;
- future sales of our common stock by existing stockholders;
- comments by securities analysts;
- general market conditions;
- fluctuations in our operating results;
- government regulation;
- 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;

## Table of Contents

- manufacturing and marketing experience; and
- production facilities.

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

*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. We are aware of a patent application controlled by another company, which if granted in its broadest scope and held to be valid, could

## [Table of Contents](#)

impact the commercialization of our modified release formulation unless we obtain a license, which may not be available to us. We are also aware of pending and issued patent claims to melanin concentrating hormone ligand and receptor, and some uses of melanocortin subtype 4 agonists. 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.

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

The use of any of our potential products in clinical trials, and the sale of any approved products, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of \$10 million per occurrence and \$10 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, juries have awarded large judgments in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us would decrease our cash reserves and could cause our stock price to fall.

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

Our research activities involve the controlled use of hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. If an accident occurs, a court may hold us liable for any resulting damages, which may harm our results of operations and 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 "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.



## [Table of Contents](#)

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 the Company's Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

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

**PART II: OTHER INFORMATION**

**ITEM 5. OTHER INFORMATION**

Effective January 1, 2005, the Compensation Committee of our Board of Directors approved the 2005 salaries of our executive officers. The salaries of our Chief Executive Officer and the other four most highly compensated executive officers (as defined under Item 402(a)(3) of Regulation S-K) of the Company, effective as of January 1, 2005 are as follows: Gary A. Lyons President, Chief Executive Officer, and Director, \$530,000; Paul W. Hawran, Executive Vice President and Chief Financial Officer, \$325,000; Henry Y. Pan, Executive Vice President Clinical Development, and Chief Medical Officer, \$359,000; Wendell Wierenga, Executive Vice President Research and Development, \$350,000; and Robert J. Little, Senior Vice President Commercial Operations, \$317,000.

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

(A) EXHIBITS.

- 31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934.
- 31.2 Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934.
- 32\* Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

(B) REPORTS ON FORM 8-K.

On January 11, 2005, the Company reported under Item 8.01 the submission of its New Drug Application for indiplon modified release tablets to update electronic formatting.

On February 7, 2005, the Company reported under Item 8.01 the resubmission plans for its New Drug Application for indiplon immediate release capsules and modified release tablets.

On February 15, 2005, the Company reported under Item 5.02 that Lawrence Steinman M.D. would not stand for re-election to the Board of Directors of the Company at the 2005 annual meeting. Dr. Steinman will continue as a scientific consultant to the Company.

**SIGNATURES**

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

Dated: May 3, 2005

/s/ Paul W. Hawran  
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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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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; and
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and
  - c) 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
  - d) 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;
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: May 3, 2005

/s/ Gary A. Lyons

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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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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; and
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and
  - c) 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
  - d) 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;
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: May 3, 2005

/s/ Paul W. Hawran

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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 March 31, 2005 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.

May 3, 2005

By: /s/ Gary A. Lyons

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 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 March 31, 2005 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.

May 3, 2005

By: /s/ Paul W. Hawran

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