

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2003

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-28150

### NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of  
incorporation or organization)

33-0525145

(IRS Employer Identification No.)

10555 SCIENCE CENTER DRIVE  
SAN DIEGO, CALIFORNIA 92121

(Address of principal executive offices)

(858) 658-7600

(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 31,268,730 as of April 25, 2003.

### NEUROCRINE BIOSCIENCES, INC.

#### FORM 10-Q INDEX

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**PART I. FINANCIAL INFORMATION**

**ITEM 1: FINANCIAL STATEMENTS**

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

|   | March 31,<br>2003  | December 31,<br>2002 |
|---|--------------------|----------------------|
|   | <i>(unaudited)</i> |                      |
| <b>ASSETS</b>   |                    |                      |
| Current assets:   |                    |                      |
| Cash and cash equivalents   | \$ 68,411          | \$ 44,313            |
| Short-term investments, available-for-sale  | 239,828            | 200,397              |
| Receivables under collaborative agreements  | 29,803             | 247                  |
| Other current assets  | 3,767              | 3,137                |
|   | 341,809            | 248,094              |
| Property and equipment, net   | 14,372             | 14,102               |
| Other non-current assets  | 6,863              | 4,343                |
|   | \$ 363,044         | \$ 266,539           |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                    |                      |
| Current liabilities:  |                    |                      |
| Accounts payable  | \$ 2,163           | \$ 1,959             |
| Accrued liabilities   | 34,602             | 22,163               |
| Deferred revenues   | 57,381             | 5,699                |
| Current portion of capital lease obligations  | 2,939              | 2,658                |
|   | 97,085             | 32,479               |
| Capital lease obligations, net of current portion   | 5,363              | 5,277                |
| Deferred rent   | 2,740              | 2,645                |
| Deferred revenues   | 41,109             | 833                  |
| Other liabilities   | 1,534              | 1,051                |
|   | 147,831            | 42,285               |
| 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 | 31                 | 31                   |

|   |                   |                   |
|---|-------------------|-------------------|
| 31,264,574 as of March 31, 2003 and 30,662,273<br>as of December 31, 2002 |                   |                   |
| Additional paid-in capital  | 428,286           | 424,084           |
| Deferred compensation   | (1,124)           | (1,240)           |
| Notes receivable from stockholders  | (208)             | (208)             |
| Accumulated other comprehensive income                                    | 3,544             | 3,513             |
| Accumulated deficit   | (215,316)         | (201,926)         |
| <b>Total stockholders' equity</b>   | <b>215,213</b>    | <b>224,254</b>    |
| <b>Total liabilities and stockholders' equity</b>                         | <b>\$ 363,044</b> | <b>\$ 266,539</b> |

See accompanying notes to the condensed financial statements.

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**NEUROCRINE BIOSCIENCES, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**(in thousands, except per share data)**

|   | <b>Three Months Ended<br/>March 31,</b> |                    |
|---|---|--------------------|
|   | <b>2003</b>                             | <b>2002</b>        |
|   | <i>(unaudited)</i>                      |                    |
| <b>Revenues:</b>  |   |                    |
| Sponsored research and development                                  | \$ 30,725                               | \$ 3,958           |
| License fees  | 6,667                                   | 583                |
| Grant income  | 324                                     | 416                |
| <b>Total revenues</b>   | <b>37,716</b>                           | <b>4,957</b>       |
| <b>Operating expenses:</b>  |   |                    |
| Research and development  | 48,324                                  | 20,047             |
| General and administrative  | 4,744                                   | 2,731              |
| <b>Total operating expenses</b>                                     | <b>53,068</b>                           | <b>22,778</b>      |
| <b>Loss from operations</b>   | <b>(15,352)</b>                         | <b>(17,821)</b>    |
| <b>Other income and (expenses):</b>                                 |   |                    |
| Interest income   | 2,201                                   | 2,045              |
| Interest expense  | (136)                                   | (101)              |
| Other income, net   | 48                                      | 113                |
| <b>Total other income and (expenses)</b>                            | <b>2,113</b>                            | <b>2,057</b>       |
| <b>Loss before income tax expense</b>                               | <b>(13,239)</b>                         | <b>(15,764)</b>    |
| Income tax expense  | 151                                     | -                  |
| <b>Net loss</b>   | <b>\$ (13,390)</b>                      | <b>\$ (15,764)</b> |
| <b>Net loss per common share:</b>                                   |   |                    |
| Basic and Diluted   | \$ (0.43)                               | \$ (0.52)          |
| <b>Shares used in the calculation of net loss per common share:</b> |   |                    |
| Basic and Diluted   | 30,789                                  | 30,384             |

See accompanying notes to the condensed financial statements.

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**NEUROCRINE BIOSCIENCES, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**

(in thousands)

|  | Three Months Ended<br>March 31, |             |
|--|---------------------------------|-------------|
|  | 2003                            | 2002        |
| <i>(unaudited)</i>   |                                 |             |
| <b>CASH FLOW FROM OPERATING ACTIVITIES</b>                                     |                                 |             |
| Net loss   | \$ (13,390)                     | \$ (15,764) |
| Adjustments to reconcile net loss to net cash<br>used in operating activities: |                                 |             |
| Depreciation and amortization  | 866                             | 700         |
| Deferred revenues  | 91,958                          | (1,037)     |
| Deferred expenses  | 578                             | 452         |
| Non-cash compensation expense  | 271                             | 225         |
| Change in operating assets and liabilities:                                    |                                 |             |
| Accounts receivable and other current assets                                   | (30,186)                        | 3,931       |
| Other non-current assets   | 78                              | (152)       |
| Accounts payable and accrued liabilities                                       | 12,643                          | (448)       |
| Net cash provided by (used in) operating activities                            | 62,818                          | (12,093)    |
| <b>CASH FLOW FROM INVESTING ACTIVITIES</b>                                     |                                 |             |
| Purchases of short-term investments  | (112,680)                       | (181,566)   |
| Sales/maturities of short-term investments                                     | 73,280                          | 81,504      |
| Deposit  | (2,500)                         | -           |
| Purchases of property and equipment  | (1,234)                         | (392)       |
| Net cash used in investing activities  | (43,134)                        | (100,454)   |
| <b>CASH FLOW FROM FINANCING ACTIVITIES</b>                                     |                                 |             |
| Issuance of common stock   | 4,047                           | 545         |
| Proceeds from capital lease financing  | 1,013                           | -           |
| Principal payments on long-term obligations                                    | (646)                           | (572)       |
| Net cash provided by (used in) financing activities                            | 4,414                           | (27)        |
| Net increase (decrease) in cash and cash equivalents                           | 24,098                          | (112,574)   |
| Cash and cash equivalents at beginning of the period                           | 44,313                          | 163,888     |
| Cash and cash equivalents at end of the period                                 | \$ 68,411                       | \$ 51,314   |

See accompanying notes to the condensed financial statements.

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

1. BASIS OF PRESENTATION

The condensed financial statements included herein are unaudited. These statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, these financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of the financial position, results of operations, and cash flows for the periods presented.

The results of operations for the interim periods 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, 2002 included in our Annual Report on Form 10-K filed with the SEC.

2. USE OF ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

### 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 Statement of Financial Accounting Standard (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 present value of the expected future cash flows associated with the use of the asset. 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, 2003.

### 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 1.9 million and 2.3 million for the period ended March 31, 2003 and 2002, respectively, and were excluded from the diluted earnings per share because of their anti-dilutive effect.

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### 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, 2003 and 2002, comprehensive loss was \$13.4 million and \$17.2 million, respectively.

### 7. REVENUE RECOGNITION

Revenue under collaborative research agreements and grants is recognized as research costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis and do not require scientific achievement as a performance obligation, and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. Up-front, nonrefundable payments for license fees and advance payments for sponsored research revenues received in excess of amounts earned are classified as deferred revenue and recognized as income over the contract or development period. Estimating the duration of the development period includes continual assessment of development stages and regulatory requirements. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events which require substantive effort. Revenues from government grants are recognized based on a percentage-of-completion basis as the related costs are incurred.

### 8. RESEARCH AND DEVELOPMENT EXPENSES

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 expenses as incurred. These expenses result from our independent R&D efforts as well as efforts associated with collaborations, grants and in-licensing arrangements. In addition, we fund R&D at other companies and research institutions under agreements, which are generally cancelable. We review and accrue clinical trials expense based on work performed, which relies on estimates of total costs incurred based on completion of patient 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.

### 9. FACILITY LEASE

In May 1997, the Company along with two unrelated parties formed Science Park Center LLC (the LLC) in order to construct an office and laboratory facility. The LLC is a California limited liability company, of which the Company owns a nominal minority interest. In relation to the construction of the facility, the Company sold a parcel of land to the LLC in exchange for a note receivable in the amount of \$3.5 million plus interest of 8.25%. The sales price was established by the fair market value of the parcel at the time of sale.

During 1998, the LLC constructed a laboratory and office facility and leased the facility to the Company under a 15-year operating lease. The Company has the option to purchase the facility at any time during the term of the lease at the unamortized cost of the first mortgage.

Based on the structure of the arrangement with the LLC, this operating lease is commonly referred to as a "synthetic lease." A synthetic lease is a form of off-balance sheet financing under which an unrelated third party funds a percentage of the costs for the acquisition and/or construction of the facility into a special purpose entity and leases the facility to a lessee. A synthetic lease is treated as an operating lease for accounting purposes and a financing lease for tax purposes. At least 3% of the third party funds must represent at-risk equity at all times. If at any time the third party fails to maintain at least 3% at-risk equity, the Company will need to consolidate the LLC. The Company selected the synthetic lease for financing advantages and periodically reviews the fair value of the property leased to determine potential accounting ramifications.

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For accounting purposes, the sale of land to the LLC does not qualify as a sale under SFAS No. 98 "Accounting for Leases," and therefore, the entire amount of the note receivable, \$2.7 million and \$2.8 million at March 31, 2003 and December 31, 2002, respectively, is included in land. The interest income earned on the note receivable from the LLC totaled approximately \$64,000 and \$56,000 for the three months ended March 31, 2003 and 2002, respectively, and is recorded as an offset to rent expense by the Company.

The Company receives disbursements from the LLC from retained earnings above and beyond the at-risk equity of the unrelated parties. The LLC accrues the disbursements payable to the Company on a monthly basis and periodically makes cash payments to reduce those payables. The disbursements due the Company are offset against rent expense recorded by the Company. Disbursements recorded by the Company for the three months ended March 31, 2003 and 2002, were \$200,000 and \$125,000, respectively.

## 10. STOCKHOLDERS' EQUITY

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

The Company has determined pro forma net loss and related per share information as if the fair value method described in 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, 2003 and 2002 (in thousands, except for loss per share data):

|  | Three Months Ended<br>March 31, |             |
|--|---------------------------------|-------------|
|  | 2003                            | 2002        |
| Net loss:                                      |                                 |             |
| As reported                                    | \$ (13,390)                     | \$ (15,764) |
| Stock option expense                           | (4,919)                         | (3,442)     |
| Pro forma net loss                             | \$ (18,309)                     | \$ (19,206) |
| Loss per share as reported (basic and diluted) | \$ (0.43)                       | \$ (0.52)   |
| Pro forma loss per share (basic and diluted)   | \$ (0.59)                       | \$ (0.63)   |

## 11. NEW ACCOUNTING PRONOUNCEMENTS

In November 2002, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. We will be required to adopt this provision for revenue arrangements entered into on or after June 30, 2003. Management is currently evaluating the effect that the adoption of EITF 00-21 will have on our results of operations and financial condition.

In January 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin No. 51." FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, we must first apply the provisions of FIN 46 for the first interim period beginning July 1, 2003. Management is currently evaluating the effect that the adoption of FIN 46 will have on its results of operations and financial position.

## 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, 2002 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, 2002.

### OVERVIEW

We incorporated in California in 1992 and reincorporated in Delaware in 1996. Since inception, we have been engaged in the discovery and development of novel pharmaceutical products for neurologic and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including insomnia, anxiety, depression, diabetes mellitus, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, auto immunity and certain female and male health disorders. To date, we have not generated any revenues from the sale of products, and we do not expect to generate any product revenues until the Food and Drug Administration (FDA) approves a drug candidate. Our lead drug candidate (indiplon) is in phase III clinical trials. We currently anticipate filing a New Drug Application (NDA) for our lead candidate early in 2004. We have funded our operations primarily through private and public offerings of our common stock and payments received under research and development agreements. We are developing a number of products with corporate collaborators and will rely on existing and future collaborators to meet funding requirements. We expect to generate future net losses in anticipation of significant

increases in operating expenses as product candidates are advanced through the various stages of clinical development. As of March 31, 2003, we have incurred a cumulative deficit of \$215.3 million and expect to incur operating losses in the future.

## CRITICAL ACCOUNTING POLICIES

Our discussion and analysis of our financial condition and results of operations is based upon financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to revenues under collaborative research agreements and grants, clinical trial accruals (R&D expense), facility lease, 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 agreements and grants are recognized as research costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis and do not require scientific achievement as a performance obligation and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. Up-front, nonrefundable payments for license fees and advance payments for sponsored research revenues received in excess of amounts earned are classified as deferred revenue and recognized as income over the contract or development period. Estimating the duration of the development period includes continual assessment of development stages and regulatory requirements. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events which require substantive effort. Revenues from government grants are recognized based on a percentage-of-completion basis as the related costs are incurred.

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Research and development (R&D) expenses include related salaries, contractor fees, facilities costs, administrative expenses and allocations of corporate costs. All such costs are charged to R&D expense as incurred. These expenses result from our independent R&D efforts as well as efforts associated with collaborations, grants and in-licensing arrangements. In addition, we fund R&D at other companies and research institutions under agreements, which are generally cancelable. We review and accrue clinical trials expenses based on work performed, which relies on estimates of total hours incurred based on completion of patient studies and other events. We follow this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

We lease our current facility under an operating lease that generally requires us to pay taxes, insurance and maintenance. Based on the structure of the arrangement, our operating lease is commonly referred to as a "synthetic lease." A synthetic lease is a form of off-balance sheet financing under which an unrelated third party funds a percentage of the costs for the acquisition and/or construction of the facility into a special purpose entity (SPE) and leases the facility to a lessee. At least 3% of the third party funds must represent at-risk equity. If at any time the third party fails to maintain at least 3% at-risk equity, we will need to consolidate the SPE. Our synthetic lease is treated as an operating lease for accounting purposes and a financing lease for tax purposes. We selected the synthetic lease for the financing advantages. Also, the agreement provides that at our option, we may purchase the building by repaying the first mortgage balance. We periodically review the fair value of the property leased to determine potential accounting ramifications.

We review long-lived assets, including leasehold improvements and property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Long-lived assets and certain identifiable intangible assets to be disposed of are reported at the lower of the carrying amount or fair value less the cost to dispose.

## RESULTS OF OPERATIONS

### THREE MONTHS ENDED MARCH 31, 2003 AND 2002

Revenues were \$37.7 million for the first quarter 2003 compared with \$5.0 million for the respective period last year. The increase in revenues for the three months ended March 31, 2003, compared with the respective period in 2002, is primarily from revenues recognized under our collaboration agreement with Pfizer, Inc (Pfizer). During the first quarter of 2003 we recognized \$29.3 million from Pfizer in the form of sponsored development funding and an additional \$5.1 million resulting from amortization of up-front license fees. Under the GlaxoSmithKline agreement, we recognized \$1.8 million in revenues this quarter compared to \$1.9 million for the same quarter last year. Revenues recognized under the Taisho Pharmaceutical Co., Ltd. (Taisho) agreement totaled \$1.1 million for the three months ended March 31, 2003 compared to \$2.3 million for the same period last year. This \$1.2 million decrease in Taisho revenue is due to the restructuring of our collaboration agreement whereby worldwide rights to our diabetes drug candidate reverted back to us.

Research and development expenses increased to \$48.3 million for the first quarter 2003 compared with \$20.0 million for the respective period in 2002. Increased expenses primarily reflect higher costs associated with expanding development activities, particularly the indiplon Phase III program (for insomnia). We currently have 16 programs in various stages of research and development, including seven programs in clinical development. Additionally, personnel and laboratory costs related to the expansion of research activities have increased during the same period. We expect research and development expense increases in the near future as later phases of development typically involve an increase in the scope of studies, the number of patients treated and the number of scientific personnel required to manage the trials.

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General and administrative expenses increased to \$4.7 million for the first quarter 2003 compared with \$2.7 million during the same period last year. The increased cost resulted primarily from increased market research and marketing related costs, increased professional fees associated with business development, increased insurance costs, and the addition of administrative personnel needed to support expanding research and development activities. We expect general and administrative costs to increase this year to provide continued support on development and clinical trials, and collaborative relationships.

Interest income increased to \$2.2 million during the first quarter of 2003 compared to \$2.0 million for the same period last year. The increase primarily resulted from higher overall investment balances offset slightly by lower interest rates.

Net loss for the first quarter of 2003 was \$13.4 million, or \$0.43 per share, compared to \$15.8 million, or \$0.52 per share, for the same period in 2002. The decrease in the net loss resulted primarily from the revenue recognized under the licensing and collaboration agreements with Pfizer. Net losses are expected to continue this year as our programs continue to advance through the various stages of the research and clinical development processes.

To date, the Company's 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 99% and 92% of our revenue for the quarters ended March 31, 2003 and 2002, respectively.

## LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2003, our cash, cash equivalents, and short-term investments totaled \$308.2 million compared with \$244.7 million at December 31, 2002. The increase in cash balances at March 31, 2003 resulted primarily from the receipt of the initial license and collaboration payments from Pfizer totaling \$100.0 million.

Net cash provided by (used in) operating activities during the first quarter of 2003 was \$62.8 million compared with (\$12.1) million during the same period last year. The increase in cash provided by operations is a result of the receipt of the initial payment under the collaboration agreement with Pfizer, offset by an increase in the receivable from collaborators due to increased clinical development costs.

Net cash used in investing activities during the first quarter of 2003 was \$43.1 million compared to \$100.5 million for the first quarter of 2002. This fluctuation resulted primarily from timing differences in investment purchases, sales and maturities and the fluctuations in our portfolio mix between cash equivalents and short-term investment holdings. We expect similar fluctuations to continue in future periods. Capital equipment purchases for 2003 are expected to be approximately \$6.0 million and will be financed primarily through leasing arrangements. Additionally, we have placed a deposit of \$3.0 million on a parcel of land, located near our current facility, which will be used to develop a new facility to allow for the future needs of the Company.

Net cash provided by financing activities during the first quarter of 2003 was \$4.4 million compared with net cash used in financing activities of \$27,000 for the respective period last year. Cash proceeds from the issuance of common stock under option programs increased by \$3.5 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. Additionally, we obtained financing for \$1.0 million of equipment purchases during the first quarter of 2003.

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.

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

## 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, 2003, 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 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. For a more detailed discussion of the factors that could cause actual results to differ, see “Item 1: Business—Risks Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

### Risks Related to the Company

#### **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 will:

- fund substantially all out of pocket costs related to future indiplon development, manufacturing and commercialization activities;
- fund a 200 person Neurocrine sales force to detail Zolofit® and, following FDA approval, 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 Pfizer to use commercially reasonable efforts in the development and commercialization of indiplon, we cannot control the amount and timing of resources Pfizer may devote to our collaboration following NDA approval in the United States nor can we control when Pfizer will seek regulatory approvals outside of the United States. If the indiplon Phase III clinical program is significantly delayed or fails 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, the indiplon market opportunity we share with Pfizer and our business may be negatively affected. 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 negatively affected.

Pfizer may terminate the collaboration at any time upon 180-days notice, subject to payment of certain amounts related to ongoing clinical development activities. If Pfizer elects to terminate the collaboration prior to FDA approval, we will be responsible for Phase III indiplon development 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 pre-clinical 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 our Phase III indiplon program is not successful, our business and reputation would be harmed and our stock price may be affected.

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In connection with the indiplon clinical trials, as well as those clinical trials of our multiple sclerosis APL, Type I diabetes APL, anxiety CRF R1 antagonist, IL-4 fusion toxin, and GnRH antagonist clinical programs, we face the risks that:

- the product may not prove to be efficacious;
- 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 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 have a material adverse effect on our business. The process of obtaining these approvals and the subsequent substantial compliance with appropriate federal and state statutes and regulations require spending substantial time and financial resources. If we fail or our collaborators or licensees fail

to obtain or maintain, or encounter delays in obtaining or maintaining, regulatory approvals, it could adversely affect the marketing of any products we develop, our ability to receive product or royalty revenues and our liquidity and capital resources. All of our products are in research and development and we have not yet requested or 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 pre-clinical 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 pre-clinical and clinical data and supporting information to the FDA for each indication to establish the product candidate's safety and efficacy. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies. Any FDA or other regulatory approval of our product candidates, once obtained, may be withdrawn. If our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments.

We plan to file a NDA for indiplon early in 2004. We face the risk that the FDA could reject our NDA filing, find it incomplete or find it insufficient for marketing approval for indiplon, which may cause our business and reputation to be harmed and could adversely affect our stock price.

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

Since our inception, we have incurred significant net losses, including net losses of \$13.4 million and \$94.5 million for the three months ended March 31, 2003 and the year ended December 31, 2002, respectively. As a result of ongoing operating losses, we had an accumulated deficit of \$215.3 million and \$201.9 million as of March 31, 2003 and December 31, 2002, respectively. We were not profitable for the year ended December 31, 2002, and we do not expect to be profitable in 2003. 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 expect to incur substantial losses for the foreseeable future. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our drugs;
- implement additional internal systems and infrastructure; and
- hire additional clinical and scientific personnel.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues to achieve and maintain profitability. 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 do 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, for among other reasons, due to our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing and contract research payments. A high proportion of our costs are fixed, due in part to our significant research and development costs. Thus, small declines in revenue could disproportionately affect operating results in a quarter. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline.

**We depend on continuing our current strategic alliances and developing additional strategic alliances to develop and commercialize our compounds.**

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 pre-clinical studies and clinical trials and obtaining required regulatory approvals for these drug candidates; and
- manufacturing and commercializing any resulting drugs.

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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 collaborations with Pfizer, GlaxoSmithKline and Wyeth. 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 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 and IL-4 fusion toxin, which we call NBI-3001, from the National Institutes of Health. In addition, we license some of the core research tools used in our collaborations from third parties, including the CRF receptor which we license from The Salk Institute and use in our CRF program collaboration with GSK and the excitatory amino acid transporters which we license from Oregon Health Sciences University and use in our EAATs collaboration with Wyeth. Other in-licensed technologies, such as the GnRH receptor which we license from Mount Sinai School of Medicine and Melanocortin subtype 4 which 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 we do not expect any of our product candidates to be commercially available within a year, if at all. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

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- be found ineffective or cause harmful side effects during pre-clinical 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.**

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

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

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

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

- continued scientific progress in our research and development programs;
- the magnitude of our research and development programs;
- progress with pre-clinical 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 manufacturing facilities and of commercialization activities and arrangements; 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 leased equipment 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.

**We have no marketing experience, sales force or distribution capabilities, and if our products are approved, we may not be able to commercialize them successfully.**

Although we do not currently have any marketable products, our ability to produce revenues ultimately depends on our ability to sell our products if and when they are approved by the FDA. We currently have no experience in marketing or selling pharmaceutical products. We are currently initiating marketing activities for indiplon by hiring staff with experience in pharmaceutical sales, marketing and distribution. We will rely on Pfizer to co-promote indiplon with us in the United States and rely exclusively on Pfizer to market indiplon outside of the United States. We will also rely on Pfizer to provide distribution, customer service, order entry, shipping, billing, customer reimbursement assistance and managed care sales support related to indiplon. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues will suffer.

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

We depend on independent clinical investigators and contract research organizations (CROs) to conduct our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, it will delay the approval of our FDA applications and our introductions of new drugs. The CROs we contract with for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our products. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may compete with us. If independent investigators and CROs assist our competitors at our expense, it could harm our competitive position.

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

We have in the past utilized, and intend to continue to utilize, third-party manufacturers to produce the drug compounds we use in our clinical trials and for the potential commercialization of our future products. We have no experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Consequently, we depend on several contract manufacturers for all production of products for development and commercial purposes. If we are unable to obtain or retain third-party manufacturers, we will not be able to commercialize our products. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations. In addition, 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 our business would be negatively impacted.

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 members of our Scientific Advisory Board and a significant number of consultants to assist us in formulating our research and development strategy. All of our consultants and members of the Scientific Advisory Board are employed by employers other than us. They may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

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

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

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

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

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

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

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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.

**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, diabetes mellitus, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, auto immunity and certain female and male 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;
- pre-clinical study and clinical testing experience;
- manufacturing and marketing experience; and

- production facilities.

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

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

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

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

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

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

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

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

We cannot assure you that third parties will not assert patent or other intellectual property infringement claims against us or our collaboration partners with respect to technologies used in potential products. Any claims that might be brought against us relating to infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit brought against us or our collaboration partners, we or our collaboration partners may 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 may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if our collaboration partners or we were able to obtain rights to the third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

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

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

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

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

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

A discussion of our exposure to, and management of, market risk appears in Part I, Item 2 of this Quarterly Report on Form 10-Q under the heading "[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 Filings and Reports is recorded, processed, summarized and reported within the timelines specified in the Security 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, to allow timely 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.

Within 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective. There have been no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date we carried out this evaluation.

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## PART II: OTHER INFORMATION

### ITEM 5. OTHER INFORMATION

#### Restructuring of Taisho Agreement

In September 2002, the collaboration agreement with Taisho was restructured to provide that Taisho's monetary and development obligations, under the collaboration agreement would terminate effective September 30, 2002 and that worldwide rights to our diabetes drug candidate, excluding Japan, revert to us. On March 31, 2003, Japanese rights to our diabetes drug candidate reverted to us.

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

- (A) EXHIBITS. There are no exhibits filed with this report.
- (B) REPORTS ON FORM 8-K. There were no current reports on Forms 8-K filed this quarter.

## SIGNATURES

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

Dated: May 1, 2003

/s/ PAUL W. HAWRAN

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

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## CERTIFICATIONS

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 quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures 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 the quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, 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 in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; 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; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: May 1, 2003

/s/ GARY A. LYONS

Gary A. Lyons  
President and Chief Executive Officer

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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 quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures 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 the quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, 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 in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; 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; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.



Dated: May 1, 2003

/s/ PAUL W. HAWRAN

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Paul W. Hawran  
Executive Vice President and  
Chief Financial Officer