# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2002

OR

Commission file number 0-28150

#### NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

#### DELAWARE

33-0525145

(State or other jurisdiction of incorporation or organization)

(IRS Employer Identification No.)

# 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_	X	No
103_		110

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 30,600,728 as of October 31, 2002.

# 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

 $(in\ thousands,\ except\ for\ share\ information)$ 

	Sept	September 30, 2002		December 31, 2001	
	(unaudited)				
ASSETS					
Current assets:					
Cash and cash equivalents	\$	56,626	\$	163,888	
Short-term investments, available-for-sale		218,281		156,094	
Receivables under collaborative agreements		2,391		9,949	
Other current assets		3,818		1,584	
Total current assets		281,116		331,515	
Property and equipment, net		13,708		12,088	
Licensed technology and patent applications costs, net		98		188	
Other non-current assets		3,721		2,559	
Total assets	\$	298,643	\$	346,350	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable	\$	3,669	\$	1,539	
Accrued liabilities		15,504		15,753	
Deferred revenues		8,219		5,382	
Current portion of long-term debt		37		149	
Current portion of capital lease obligations		2,179		1,938	
Total current liabilities		29,608		24,76	
Capital lease obligations, net of current portion		4,473		3,60	
Deferred rent		2,551		2,190	
Deferred revenues		1,208		4,417	
Other liabilities		972		983	
Total liabilities		38,812		35,957	
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					
30,582,614 as of September 30, 2002 and 30,347,744					
as of December 31, 2001		31		3	

Additional paid-in capital	422,205	420,018
Deferred compensation	(1,361)	(1,815)
Notes receivable from stockholders	(277)	(381)
Accumulated other comprehensive income (loss)	2,372	(69)
Accumulated deficit	(163,139)	(107,390)
Total stockholders' equity	259,831	310,393
Total liabilities and stockholders' equity	\$ 298,643 \$	346,350

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)

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2002		2001		2002		2001
		(unaud	ited)			(unaud	ited)	
Revenues:								
Sponsored research and development	\$	3,574	\$	5,104	\$	10,712	\$	10,948
License fees		581		501		1,747		959
Milestones		250		15,500		250		15,500
Grant income		578		488		1,458		1,002
Total revenues		4,983		21,593		14,167		28,409
Operating expenses:								
Research and development		24,231		18,327		67,374		49,583
General and administrative		3,253		2,073		9,135		7,304
Total operating expenses		27,484		20,400		76,509		56,887
(Loss) income from operations		(22,501)		1,193		(62,342)		(28,478)
Other income and (expenses):								
Interest income		2,458		1,254		6,785		5,965
Interest expense		(175)		(79)		(367)		(223)
Other income and (expenses), net		(16)		139		175		436
Total other income and (expenses)		2,267		1,314		6,593		6,178
Net (loss) income	\$	(20,234)	\$	2,507	\$	(55,749)	\$	(22,300)
Net (loss) income per common share:								
Basic	\$	(0.66)	\$	0.10	\$	(1.83)	\$	(0.87)
Diluted	\$	(0.66)	\$	0.09	\$	(1.83)	\$	(0.87)
Shares used in the calculation of net (loss) income per common share:								
Basic		30,522		25,816		30,447		25,575
Diluted		30,522		27,972		30,447		25,575

See accompanying notes to the condensed financial statements.

	2002		2001 ited)	
	(una	udited)		
CASH FLOW FROM OPERATING ACTIVITIES				
Net loss	\$ (55,749)	\$	(22,300)	
Adjustments to reconcile net loss to net cash				
used in operating activities:				
Loss on abandonment of assets	-		51	
Depreciation and amortization	2,188		1,918	
Deferred revenues	(372)		9,177	
Deferred expenses	404		352	
Non-cash compensation expense	692		1,585	
Change in operating assets and liabilities:				
Accounts receivable and other current assets	5,324		(13,680)	
Other non-current assets	(886)		(238)	
Accounts payable and accrued liabilities	1,821		1,188	
Net cash used in operating activities	(46,578)		(21,947)	
CASH FLOW FROM INVESTING ACTIVITIES				
Purchases of short-term investments	(331,858)		(73,953)	
Sales/maturities of short-term investments	272,112		87,930	
Purchases of property and equipment	(3,994)		(3,459)	
Net cash (used in) provided by investing activities	(63,740)		10,518	
CASH FLOW FROM FINANCING ACTIVITIES				
Issuance of common stock	1,950		2,431	
Proceeds from capital lease financing	2,742		1,011	
Principal payments on long-term obligations	(1,740)		(1,145)	
Payments received on notes receivable from stockholders	104		-	
Net cash provided by financing activities	3,056		2,297	
Net decrease in cash and cash equivalents	(107,262)		(9,132)	
Cash and cash equivalents at beginning of the period	163,888		21,078	
Cash and cash equivalents at end of the period	\$ 56,626	\$	11,946	

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 for the year ended December 31, 2001 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 reported in other income and expenses. 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 September 30, 2002.

#### 5. (LOSS) INCOME PER COMMON SHARE

The Company computes net (loss) income per share in accordance with SFAS No. 128, "Earnings Per Share." Under the provisions of SFAS No. 128, basic net (loss) income per share is computed by dividing the net (loss) income for the period by the weighted average number of common shares outstanding during the period. Diluted net (loss) income per share is computed by dividing the net (loss) income for the period by the weighted average number of common and common equivalent shares outstanding during the period. Except for the quarter ended September 30, 2001, potentially dilutive securities, composed of incremental common shares issuable upon the exercise of stock options and warrants, were excluded from historical diluted (loss) income per share because of their anti-dilutive effect.

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#### 6. COMPREHENSIVE INCOME (LOSS)

Comprehensive income (loss) is calculated in accordance with SFAS No. 130, "Comprehensive Income." SFAS No. 130 requires the disclosure of all components of comprehensive income (loss), including net income (loss) and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. The Company's other comprehensive income (loss) consists of gains and losses on short-term investments and is reported in the statements of stockholders' equity. For the three months ended September 30, 2002 and 2001, comprehensive loss was \$18.3 million and comprehensive income was \$2.1 million, respectively. For the nine months ended September 30, 2002 and 2001, comprehensive loss was \$53.3 million and \$22.6 million, respectively.

# 7. REVENUE RECOGNITION

In accordance with Staff Accounting Bulletin (SAB) No. 101, "Revenue Recognition in Financial Statements," 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 received in excess of amounts earned are classified as deferred revenue and recognized as income over the period earned. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events. Revenues from government grants are recognized based on a percentage-of-completion basis as the related costs are incurred. The Company recognizes revenue only on payments that are nonrefundable and when the work is performed.

# 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 hours incurred and completion of certain 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 up to 100% of the costs for the acquisition and/or construction of the facility into a limited liability company 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 represent at-risk equity and must remain at-risk to qualify as an operating lease for accounting purposes. If at any time the third party fails to maintain at least 3% at-risk equity, the Company will need to consolidate the LLC, which will result in debt and equity being recorded in its financial statements. The Company selected the synthetic lease for financing advantages and periodically reviews the fair value of the property leased to determine potential accounting ramifications.

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, \$2.9 million and \$3.2 million at September 30, 2002 and December 31, 2001, respectively, is included in land. The interest income earned on the note receivable from the LLC totaled approximately \$186,000 and \$298,000 for the nine months ended September 30, 2002 and the year ended December 31, 2001, 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 nine months ended September 30, 2002 and the year ended December 31, 2001, were \$0.9 million and \$1.1 million, respectively.

#### 10. NEW ACCOUNTING PRONOUNCEMENTS

In June 2002, the Financial Accounting Standards Board issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities". SFAS No. 146 addresses the recognition, measurement and reporting costs that are associated with exit or disposal activities. SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The Company does not expect the adoption of SFAS No. 146 to have a material effect on its financial statements.

# 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, 2001 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, 2001.

#### **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, malignant brain tumors and peripheral cancers, diabetes, mellitus, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, stroke, and certain female 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 late in 2003. 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 September 30, 2002, we have incurred a cumulative deficit of \$163.1 million and expect to incur operating losses in the future, which may be greater than losses in prior years.

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#### CRITICAL ACCOUNTING POLICES

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, 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 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 period earned. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events. Revenues from government grants are recognized based on a percentage-of-completion basis as the related costs are incurred. We recognize revenue only on payments that are nonrefundable and when the work is performed.

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 and completion of certain 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 trails 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 up to 100% 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 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, which will result in debt and equity being recorded in our financial statements. 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.

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#### RESULTS OF OPERATIONS

#### THREE MONTHS ENDED SEPTEMBER 30, 2002 AND 2001

Revenues for the third quarter of 2002 were \$5.0 million compared with \$21.6 million for the same period last year. The decrease in revenues for the three months ended September 30, 2002, compared with the respective period in 2001, is primarily due to the recognition of \$15.5 million of revenue in connection with a milestone achievement in 2001 under our collaboration agreement with GlaxoSmithKline (GSK). The GSK agreement started in the third quarter of 2001 and provides for license fees, milestones and sponsored research & development funding. Revenues this quarter were \$2.1 million under the GSK agreement compared to \$17.1 in the third quarter of 2001. Revenues under our collaboration agreement with Taisho, which include license fees, milestones and sponsored research & development funding, decreased to \$2.0 million this quarter from \$3.2 million for the same quarter last year. Excluding the milestone payment from GSK last year, total revenues for the third quarter of 2002 decreased by \$1.1 million compared to the same period last year, primarily due to timing of reimbursable development expenses, and restructuring of the Taisho collaboration agreement.

In April 2002, we commenced discussions with Taisho to restructure our collaboration agreement with them. At that time we agreed that Taisho's monetary and development obligations, under the collaboration agreement, may terminate on September 30, 2002.

In September 2002, the collaboration agreement with Taisho was further restructured to provide that worldwide rights, excluding Japan, revert to us. The restructuring agreement further provides that under certain circumstances, if we enter into a business arrangement with specified third parties, then Taisho will be entitled to receive a percentage of certain consideration received by us. Generally, if we do not enter into a business discussion with one of the specified third parties on or before a specified date, the restructured agreement will expire, and at that time the rights to Japan will revert to us.

Research and development expenses increased to \$24.2 million for the third quarter of 2002 compared with \$18.3 million for the respective period in 2001. Increased expenses primarily reflect higher costs associated with expanding development activities, particularly the indiplon phase III program (for insomnia). We expect to incur significant increases in future periods because 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.

General and administrative expenses increased to \$3.3 million for the third quarter of 2002 compared with \$2.1 million during the same period last year. The increase in administrative expenses resulted primarily from, increased marketing research and marketing related costs, increased recruiting and relocation costs for scientists and researchers, 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 moderately this year to provide continued support of our research and clinical development efforts.

Interest income increased to \$2.5 million during the third quarter of 2002 compared to \$1.3 million for the same period last year. The increase is primarily due to higher investment balances, partially offset by declining interest rate yields during the third quarter of 2002 compared to the same period last year. Investment balances in 2002 were increased by the sale of 4.0 million shares of our common stock in a December 2001 public offering. Net proceeds received from the offering were \$175.6 million. Due to lower interest rates, we expect interest income for this year to be similar to that of last year.

Net loss for the third quarter of 2002 was \$20.2 million, or \$0.66 per share, compared to net income of \$2.5 million, or \$0.10 per share, for the same period in 2001. The increase in net loss is primarily due to the recognition of \$15.5 million of revenue in connection with a milestone achievement in 2001 under the GSK agreement and increased expenses in 2002 related to expanded clinical programs, particularly our indiplon program. We expect our net losses to increase this year as our programs continue to advance through the various stages of the research and clinical development processes.

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To date, our revenues have come from funded research and achievements of milestones under corporate collaborations. 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. Revenues from collaborations accounted for 88% and 98% of total revenues for the quarters ended September 30, 2002 and 2001, respectively.

#### NINE MONTHS ENDED SEPTEMBER 30, 2002 AND 2001

Revenues for the nine months ended September 30, 2002 were \$14.2 million compared with \$28.4 million in 2001. The decrease in revenues for the nine months ended September 30, 2002 resulted primarily from the recognition of a \$15.5 million milestone achievement in 2001 under the GSK agreement. Under the GSK agreement, we recognized \$5.7 million in revenues for the nine months ended September 30, 2002 compared to \$17.1 million for the same period last year. Revenues under the Wyeth agreement decreased to \$1.1 million this period compared to \$2.3 million during the same period last year. The three-year sponsored research portion of the Wyeth agreement was completed on schedule in December 2001 and was subsequently extended on a smaller scale through December 2002. Revenue under our collaboration agreement with Taisho decreased to \$5.8 million from \$7.6 million for the nine months ended September 30, 2002 and

2001, respectively. Excluding the milestone revenue from GSK last year, total revenues for the nine months ended September 30, 2002 increased by \$1.3 million over the same period last year.

In April 2002, we commenced discussions with Taisho to restructure our collaboration agreement with them. At that time we agreed that Taisho's monetary and development obligations, under the collaboration agreement, may terminate on September 30, 2002.

In September 2002, the collaboration agreement with Taisho was further restructured to provide that worldwide rights, excluding Japan, revert to us. The restructuring agreement further provides that under certain circumstances, if we enter into a business arrangement with specified third parties, then Taisho will be entitled to receive a percentage of certain consideration received by us. Generally, if we do not enter into a business discussion with one of the specified third parties on or before a specified date, the restructured agreement will expire, and at that time the rights to Japan will revert to us

Research and development expenses increased to \$67.4 million for the first nine months of 2002 compared with \$49.6 million for the respective period in 2001. Increased expenses primarily reflect higher costs associated with expanding development activities, particularly the indiplon Phase III program (for insomnia). We expect to incur significant increases in future periods because 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 clinical trials.

General and administrative expenses increased to \$9.1 million for the nine months ended September 30, 2002 compared with \$7.3 million during the same period last year. The increase in administrative expenses resulted primarily from increased marketing research and marketing related costs, increased recruiting and relocation costs for scientists and researchers, increased insurance costs, and the addition of administrative personnel needed to support expanding research and development activities. We expect general and administration costs to increase moderately this year to provide continued support of our research and clinical development efforts.

Interest income increased to \$6.8 million for the nine months ended September 30, 2002 compared to \$6.0 million for the same period last year. The increase is primarily due to higher investment balances during 2002 compared to the same period last year. Investment balances in 2002 were increased by the sale of 4.0 million shares of our common stock in a December 2001 public offering. Net proceeds received from the offering were \$175.6 million. Due to declining interest rate yields, we expect interest income for this year to be similar to that of last year.

Net loss for the first nine months of 2002 was \$55.7 million, or \$1.83 per share, compared to \$22.3 million, or \$0.87 per share, for the same period in 2001. The increase in net loss is primarily due to the recognition of \$15.5 million of revenue in connection with a milestone achievement in 2001 under the GSK agreement and increased expenses in 2002 related to expanded clinical programs, particularly our indiplon program. We expect our net losses to increase this year as our programs continue to advance through the various stages of the research and clinical development processes.

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To date, our revenues have primarily come from funded research and achievements of milestones under corporate collaborations. 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. Revenues from collaborations accounted for 90% and 96% of total revenues for the nine months ended September 30, 2002 and 2001, respectively.

# LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2002, our cash, cash equivalents, and short-term investments totaled \$274.9 million compared with \$320.0 million at December 31, 2001. The decrease in cash balances at September 30, 2002 resulted primarily from the funding of research and development efforts, particularly, the support of multiple products in various phases of clinical development.

Net cash used in operating activities during the nine months ended September 30, 2002 was \$46.6 million compared with \$21.9 million during the same period last year. The increase in cash used in operations resulted primarily from the increase in clinical development activities.

Net cash used in investing activities during the nine months ended September 30, 2002 was \$63.7 million compared to net cash provided by investing activities of \$10.5 million for the same period last year. This fluctuation resulted primarily from the timing differences in the investment purchases, sales and maturities of investments 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 2002 are expected to be approximately \$6.9 million and will be financed primarily through leasing arrangements.

Net cash provided by financing activities during the first nine months of 2002 was \$3.1 million compared to \$2.3 million for the same period last year. Cash proceeds from the issuance of common stock under option and employee purchase programs was \$2.0 million and \$2.4 million in the nine months ended September 30, 2002 and 2001, respectively. Additionally, we financed \$2.7 million and \$1.0 million in capital expenditures for the nine months ended September 30, 2002 and 2001, respectively. 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.

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 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 pre-clinical 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, pre-clinical 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.

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#### INTEREST RATE RISK

We are exposed to interest rate risk on our short-term investments. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest in short-term securities and ensure that the maximum average maturity of our investments does not exceed 40 months. If a 10% change in interest rates were to have occurred on September 30, 2002, 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.

#### CAUTION ON FORWARD-LOOKING STATEMENTS

This Quarterly Report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, which provides a "safe harbor" for these types of statements. To the extent statements in this Quarterly Report involve, without limitation, our expectations regarding the continuation of our collaboration agreements, the receipt of research payments thereunder, the future achievement of various milestones in product development and the receipt of payments related thereto, the potential receipt of royalty payments, pre-clinical testing and clinical trials of potential products, the period of time that our existing capital resources will meet our funding requirements, or any other guidance on future periods, these statements are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan" and "would." 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" and other risks identified from time to time in our filings with the Securities and Exchange Commission, press releases and other communications. We undertake no obligation to release publicly the results of any revisions to these forward-looking statements or to reflect events or circumstances arising after the date hereof.

#### 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, 2001.

#### Risks Related to the Company

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

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.

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:

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

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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 in December 2003. We face the risk that the FDA could reject our NDA filing, find it incomplete or find it insufficient for marketing approval for indiplon, our business and reputation would be harmed and our stock price may be affected.

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 \$55.7 million and \$36.9 million for the nine months ended September 30, 2002 and the year ended December 31, 2001, respectively. As a result of ongoing operating losses, we had an accumulated deficit of \$163.1 million and \$107.4 million as of September 30, 2002 and December 31, 2001, respectively. We do not expect to be profitable in 2002. 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.

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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.

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.

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 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 Pharmaceuticals 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.

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Because the development of our product candidates is subject to a substantial degree of technological uncertainty, we may not succeed in developing any of our product candidates.

All of our product candidates are in research or development and we do not expect any of our product candidates to be commercially available for the foreseeable future, if at all. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

- be found ineffective or cause harmful side effects during 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 these potential problems occurs, we may never successfully market any products.

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;
- $\bullet \quad \text{the cost of manufacturing facilities and of commercialization activities and arrangements; and} \\$
- 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.

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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. 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; and
- 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.

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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 will 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 will also be 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.

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, malignant brain tumors and peripheral cancers, diabetes, mellitus, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, stroke, and certain female disorders, and there are a number of competitors to products in our research pipeline. If one or more of these 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.

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.

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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.

#### 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.

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#### 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.

- a. 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.
- b. 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.

# PART II: OTHER INFORMATION

#### ITEM 5. OTHER INFORMATION

# **Restructuring of Taisho Agreement**

In April 2002, we commenced discussions with Taisho to restructure our collaboration agreement with them. At that time we agreed that Taisho's monetary and development obligations, under the collaboration agreement, may terminate on September 30, 2002.

In September 2002, the collaboration agreement with Taisho was further restructured to provide that worldwide rights, excluding Japan, revert to us. The restructuring agreement further provides that under certain circumstances, if we enter into a business arrangement with specified third parties, then Taisho will be entitled to receive a percentage of certain consideration received by us. Generally, if we do not enter into a business discussion with one of the specified third parties on or before a specified date, the restructured agreement will expire, and at that time the rights to Japan will revert to us.

#### 2001 Stock Option Plan

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#### **Board of Directors Compensation**

On October 14, 2002, the Board of Directors amended the amount of cash compensation a Director receives to provide to each Director who is not an employee or consultant of us an annual retainer of \$15,000 plus a retainer of \$2,500 for each member of the Audit Committee, Compensation Committee and Nomination/Corporate Governance Committee. The Chairman of the Audit Committee will be provided an additional retainer of \$2,500. Board members will continue to receive \$1,000 for each meeting of the Board of Directors. No Board member will receive more than \$5,000 in committee retainers in any fiscal year. The amendment to the cash compensation that Directors will receive, results in an increase in the annual retainer for Directors who are not employees or consultants of us from \$10,000 to \$15,000. It also provides for newly approved retainers for service on the Audit, Compensation, and Nominating/Corporate Governance Committees.

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

#### (A) EXHIBTIS.

Exhibit	
<u>Number</u>	<u>Description</u>
4.1	Neurocrine Biosciences, Inc. 2001 Stock Option Plan, as amended.
10.1†	Restructuring Agreement, dated September 30, 2002, between Taisho
	Pharmaceutical Co., Ltd. and Neurocrine Biosciences, Inc.

† A request for confidential treatment with respect to portions of this exhibit which have been omitted (indicated by asterisks) pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 is currently pending.

(B) REPORTS ON FORM 8-K. A report on Form 8-K filed August 14, 2002, reporting under Item 9 the announcement that Neurocrine Biosciences, Inc. submitted to the Securities and Exchange Commission the certifications by the Principal Executive Officer and Principal Financial Officer required by Section 906 of the Sarbanes-Oxley Act of 2002.

### **Signatures**

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

Dated: November 13, 2002 /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: November 13, 2002

/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: November 13, 2002

/s/ PAUL W. HAWRAN

Paul W. Hawran Executive Vice President and Chief Financial Officer

#### NEUROCRINE BIOSCIENCES, INC.

#### 2001 STOCK OPTION PLAN

#### As Amended August 6, 2002 and October 15, 2002

1. <u>Purpose of the Plan.</u> The purposes of this Incentive Stock Plan are to attract and retain the best available personnel, to provide additional incentive to the employees of Neurocrine Biosciences, Inc. (the "Company") and to promote the success of the Company's business.

## 2. **Definitions.**

- a. "Board" shall mean the Committee, if one has been appointed, or the Board of Directors of the Company, if no Committee is appointed.
- b. "Code" shall mean the Internal Revenue Code of 1986, as amended.
- C. "Committee" shall mean the Committee appointed by the Board of Directors in accordance with Section 4(a) of the Plan, if one is appointed.
- d. "Common Stock" shall mean the common stock, \$.001 per share, of the Company.
- e. "Company" shall mean Neurocrine Biosciences, Inc.
- f. "Consultant" shall mean any person who is engaged by the Company or any Parent or Subsidiary to render consulting services and is compensated for such consulting services, and any director of the Company whether compensated for such services; provided that (i) such person renders bona fide services to the Company, (ii) the services rendered by such person are not in connection with the offer or sale of securities in a capital-raising transaction and do not directly or indirectly promote or maintain a market for the Company's securities, and (iii) such person is a natural person who has contracted directly with the Company to render such services. However, the term "Consultant" shall not include members of the Board of Directors of the Company who are either not compensated by the Company for their services as directors or who are merely paid a fee by the Company for their services as directors.
- g. "Continuous Status as an Employee or Consultant" shall mean the absence of any interruption or termination of service as an Employee or Consultant, as applicable. Continuous Status as an Employee or Consultant shall not be considered interrupted in the case of sick leave, military leave, or any other leave of absence approved by the Board; provided that such leave is for a period of not more than ninety (90) days or reemployment upon the expiration of such leave is guaranteed by contract or statute. Continuous Service shall not be deemed to have terminated merely because of a change in the capacity in which the Optionee renders service to the Company as an Employee or Consultant, provided that the Optionee's service is continuous.
- h. "<u>Employee</u>" means any person employed by the Company. Mere service as a member of the Board of Directors or payment of a director's fee by the Company shall not be sufficient to constitute "employment" by the Company.
- i. "Fair Market Value" means, as of any date, the value of the Common Stock determined as follows:
  - i. If the Common Stock is listed on any established stock exchange or traded on the Nasdaq National Market or the Nasdaq SmallCap Market, the Fair Market Value of a share of Common Stock shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the last market trading day prior to the day of determination, as reported by The Nasdaq Stock Market or such other source as the Board deems reliable.
  - ii. In the absence of such markets for the Common Stock, the Fair Market Value shall be determined in good faith by the Board.
- j. "Nonstatutory Stock Option" shall mean an Option not intended to qualify as an incentive stock option within the meaning of Section 422 of the Code.
- k. "Officer" means a President, Secretary, Treasurer, Chairman of the Board, Vice President, Assistant Secretary or Assistant Treasurer of the Company, as such positions are described in the Company's Bylaws, any other person designated an "officer" of the Company by the Board of Directors in accordance with the Company's Bylaws or any person who is an "officer" within the meaning of Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended, or Nasdaq Marketplace Rule 4350(i)(1)(A).
- l. "Option" shall mean a stock option granted pursuant to the Plan.
- m. "Optioned Stock" shall mean the Common Stock subject to an Option or Stock Purchase Right.
- n. "Optionee" shall mean an Employee or Consultant who receives an Option.
- O. "Parent" shall mean a "parent corporation," whether now or hereafter existing, as defined in Section 424(e) of the Code.

- p. "Plan" shall mean this 2001 Incentive Stock Plan.
- q. "Purchaser" shall mean an Employee or Consultant who exercises a Stock Purchase Right.
- r. "Share" shall mean a share of the Common Stock, as adjusted in accordance with Section 12 of the Plan.
- S. "Stock Purchase Right" shall mean a right to purchase Common Stock pursuant to the Plan or the right to receive a bonus of Common Stock for past services.
- t. "Subsidiary" shall mean a "subsidiary corporation," whether now or hereafter existing, as defined in Section 424(f) of the Code.
- 3. Stock Subject to the Plan. Subject to the provisions of Section 12 of the Plan, the maximum aggregate number of shares that may be issued upon exercise of Options and Stock Purchase Rights under the Plan is one million, one hundred fifty thousand (1,150,000) shares of Common Stock. The Shares may be authorized but unissued, or reacquired Common Stock. If an Option or Stock Purchase Right should expire or become unexercisable for any reason without having been exercised in full, then the unpurchased Shares which were subject thereto shall, unless the Plan shall have been terminated, become available for future grant or sale under the Plan. Notwithstanding any other provision of the Plan, shares issued under the Plan and later repurchased by the Company shall not become available for future grant or sale under the Plan.

#### 4. Administration of the Plan.

#### a. Procedure.

- i. <u>Multiple Administrative Bodies.</u> The Plan may be administered by different Committees with respect to different groups of Employees and Consultants.
- ii. <u>Section 162(m)</u>. To the extent that the Administrator determines it to be desirable to qualify Options granted hereunder as "performance-based compensation" within the meaning of Section 162(m) of the Code, the Plan shall be administered by a Committee of two or more "outside directors" within the meaning of Section 162(m) of the Code.
- iii. <u>Rule 16b-3</u>. To the extent desirable to qualify transactions hereunder as exempt under Rule 16b-3, the transactions contemplated hereunder shall be structured to satisfy the requirements for exemption under Rule 16b-3.
- iv. Other Administration. Other than as provided above, the Plan shall be administered by (A) the Board or (B) a Committee, which committee shall be constituted to satisfy applicable laws.
- b. Powers of the Board. Subject to the provisions of the Plan, the Board shall have the authority, in its discretion: (i) to grant Nonstatutory Stock Options or Stock Purchase Rights; (ii) to determine, upon review of relevant information and in accordance with Section 7 of the Plan, the Fair Market Value of the Common Stock; (iii) to determine the exercise price per share of Options or Stock Purchase Rights, to be granted, which exercise price shall be determined in accordance with Section 7 of the Plan; (iv) to determine, subject to Section 5 below, the Employees or Consultants to whom, and the time or times at which, Options or Stock Purchase Rights shall be granted and the number of shares to be represented by each Option or Stock Purchase Right; (v) to interpret the Plan; (vi) to prescribe, amend and rescind rules and regulations relating to the Plan; (vii) to determine the terms and provisions of each Option and Stock Purchase Right granted (which need not be identical) and, with the consent of the holder thereof, modify or amend any provisions (including provisions relating to exercise price) of any Option or Stock Purchase Right; (viii) to accelerate or defer (with the consent of the Optionee) the exercise date of any Option, consistent with the provisions of Section 5 of the Plan; (ix) to authorize any person to execute on behalf of the Company any instrument required to effectuate the grant of an Option or Stock Purchase Right previously granted by the Board; (x) to allow Optionees to satisfy withholding tax obligations by electing to have the Company withhold from the Shares to be issued upon exercise of an Option or Stock Purchase Right that number of Shares having a Fair Market Value equal to the statutory minimum amount required to be withheld. The Fair Market Value of the Shares to be withheld shall be determined on the date that the amount of tax to be withheld is to be determined. All elections by an Optionee to have Shares withheld for this purpose shall be made in such form and under such conditions as the Administrator may deem necessary or advisable; and (xi) to make all other determinations deemed necessary or advisable for the administration of the Plan.
- C. <u>Effect of Board's Decision.</u> All decisions, determinations and interpretations of the Board shall be final and binding on all Optionees, Purchasers and any other holders of any Options or Stock Purchase Rights granted under the Plan.

# 5. Eligibility.

- a. Options and Stock Purchase Rights may be granted to Employees and Consultants. An Employee or Consultant who has been granted an Option or Stock Purchase Right may, if such Employee or Consultant is otherwise eligible, be granted additional Option(s) or Stock Purchase Right(s). Notwithstanding anything herein to the contrary, the aggregate number of shares issued or reserved for issuance pursuant to Options granted to persons other than Officers must exceed fifty percent (50%) of the total number of shares issued or reserved for issuance pursuant to Options granted under the Plan as determined on the three-year anniversary of the adoption of the Plan by the Board and on each yearly anniversary of the adoption of the Plan thereafter.
- b. Each Option shall be designated in the written option agreement as a Nonstatutory Stock Option.
- c. The Plan shall not confer upon any Optionee or holder of a Stock Purchase Right any right with respect to continuation of employment by or the rendition of consulting services to the Company, nor shall it interfere in any way with his or her right or the Company's right to terminate his or

her employment or services at any time, with or without cause.

- d. A Consultant shall not be eligible for the grant of an Option if, at the time of grant, a Form S-8 Registration Statement under the Securities Act ("Form S-8") is not available to register either the offer or the sale of the Company's securities to such Consultant because of the nature of the services that the Consultant is providing to the Company, or because the Consultant is not a natural person, or as otherwise provided by the rules governing the use of Form S-8, unless the Company determines both (i) that such grant (A) shall be registered in another manner under the Securities Act (e.g., on a Form S-3 Registration Statement) or (B) does not require registration under the Securities Act in order to comply with the requirements of the Securities Act, if applicable, and (ii) that such grant complies with the securities laws of all other relevant jurisdictions
- 6. <u>Term of Plan.</u> The Plan shall become effective upon the earlier to occur of its adoption by the Board of Directors. It shall continue in effect for a term of ten (10) years unless sooner terminated under Section 14 of the Plan.

## 7. Exercise Price and Consideration.

- **a.** The per Share exercise price for the Shares to be issued pursuant to exercise of an Option or Stock Purchase Right shall be such price as is determined by the Board, but shall be subject to the following:
  - i. the per Share exercise price shall be no less than the par value per Share on the date of grant.
- b. The consideration to be paid for the Shares to be issued upon exercise of an Option or Stock Purchase Right, including the method of payment, shall be determined by the Board and may consist entirely of cash, check, promissory note bearing a market rate of interest, other Shares of Common Stock which (i) either have been owned by the Optionee for more than six (6) months on the date of surrender or were not acquired directly or indirectly, from the Company, and (ii) have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which said Option shall be exercised, or any combination of such methods of payment, or such other consideration and method of payment for the issuance of Shares as may be permitted under applicable law.
- 8. <u>Term of Option.</u> The term of each Option shall be the term stated in the Option Agreement; provided, however, that the term shall be no more than ten (10) years from the date of grant thereof.

#### 9. Exercise of Option.

- a. Procedure for Exercise; Rights as a Shareholder.
  - i. Any Option granted hereunder shall be exercisable at such times and under such conditions as determined by the Board, including performance criteria with respect to the Company and/or the Optionee, and as shall be permissible under the terms of the Plan.
  - ii. An Option may not be exercised for a fraction of a Share.
  - iii. An Option shall be deemed to be exercised when written notice of such exercise has been given to the Company in accordance with the terms of the Option by the person entitled to exercise the Option and full payment for the Shares with respect to which the Option is exercised has been received by the Company. Full payment may, as authorized by the Board, consist of any consideration and method of payment allowable under Section 7 of, the Plan. Until the issuance (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company) of the stock certificate evidencing such Shares no right to vote or receive dividends or any other rights as a shareholder shall exist with respect to the Optioned Sock, notwithstanding the exercise of the Option. The Company shall issue (or cause to be issued) such stock certificate promptly upon exercise of the Option. No adjustment will be made for a dividend or other right for which the record date is prior to the date the stock certificate is issued, except as provided in Section 12 of the Plan.
  - iv. Exercise of an Option in any manner shall result in a decrease in the number of Shares which thereafter may be available, both for purposes of the Plan and for sale under the Option, by the number of Shares as to which the Option is exercised.
- b. <u>Termination of Status as an Employee or Consultant</u>. In the event of termination of an Optionee's Continuous Status as an Employee or Consultant (as the case may be), such Optionee may, but only within such period of time as is determined by the Board, with such determination not exceeding six (6) months after the date of termination, exercise the Option to the extent that such Employee or Consultant was entitled to exercise it at the date of such termination (but in no event later than the date of expiration of the term of such Option as set forth in the Option Agreement). To the extent that such Employee or Consultant was not entitled to exercise the Option at the date of such termination, or if such Employee or Consultant does not exercise such Option (which such Employee or Consultant was entitled to exercise) within the time specified herein, the Option shall terminate.
- C. <u>Disability of Optionee</u>. Notwithstanding the provisions of Section 8(b)(ii) above, in the event of termination of an Optionee's Continuous Status as an Employee or Consultant as a result of such Employee's or Consultant's total and permanent disability (as defined in Section 22(e)(3) of the Code), such Employee or Consultant may, but only within six (6) months (or such other period of time as is determined by the Board) from the date of such termination (but in no event later than the date of expiration of the term of such Option as set forth in the Option Agreement), exercise the Option to the extent the right to exercise would have accrued had the Optionee continued Continuous Status as an Employee or Consultant for a period of six (6) months following termination of Continuous Status by reason of disability. To the extent that such Employee or Consultant was not entitled to exercise an Option in this period, or if such Employee or Consultant does not exercise such Option (which such Employee or Consultant was entitled to exercise) within the time specified herein, the Option shall terminate.

- d. Retirement of Optionee. Notwithstanding the provisions of Section 8(b)(ii) above, in the event of termination of an Employee Optionee's Continuous Status as an Employee as a result of such Employee's retirement from the Company at age fifty five (55) or greater after having Continuous Status for (5) years or more, all Options held by such Optionee shall vest and such Employee may, but only within three (3) years from the date of such termination (but in no event later than the date of expiration of the term of such Option as set forth in the Option Agreement), exercise the Option to the extent such Employee was entitled to exercise it at the date of such termination.
- e. Death of Optionee. In the event of the death of an Optionee:
  - i. during the term of the Option who is at the time of his or her death an Employee or Consultant of the Company and who shall have been in Continuous Status as an Employee or Consultant since the date of grant of the Option, the Option may be exercised, at any time within six (6) months (or at such later time as may be determined by the Board but in no event later than the date of expiration of the term of such Option as set forth in the Option Agreement), by the Optionee's estate or by a person who acquired the right to exercise the Option by bequest or inheritance, but only to the extent that the right to exercise would have accrued had the Optionee continued living and remained in Continuous Status as an Employee or Consultant six (6) months (or such other period of time as in determined by the Board) after the date of death; or
  - ii. within thirty (30) days (or such other period of time as is determined by the Board), after the termination of Continuous Status as an Employee or Consultant, the Option may be exercised, at any time within six (6) months (or such other period of time as is determined by the Board at the time of grant of the Option) following the date of death (but in no event later than the date of expiration of the term of such Option as set forth in the Option Agreement), by the Optionee's estate or by a person who acquired the right to exercise the Option by bequest or inheritance, but only to the extent that the right to exercise that had accrued at the date of termination.

#### 10. Stock Purchase Rights.

- a. <u>Rights to Purchase</u>. After the Board of Directors determines that it will offer an Employee or Consultant a Stock Purchase Right, it shall deliver to the offeree a stock purchase agreement or stock bonus agreement, as the case may be, setting forth the terms, conditions and restrictions relating to the offer, including the number of Shares which such person shall be entitled to purchase, and the time within which such person must accept such offer, which shall in no event exceed six (6) months from the date upon which the Board of Directors or its Committee made the determination to grant the Stock Purchase Right. The offer shall be accepted by execution of a stock purchase agreement or stock bonus agreement in the from determined by the Board of Directors.
- b. <u>Issuance of Shares</u>. Forthwith after payment therefor, the Shares purchased shall be duly issued; provided, however, that the Board may require that the Purchaser make adequate provision for any Federal and State withholding obligations of the Company as a condition to the Purchaser purchasing such Shares.
- c. <u>Repurchase Option</u>. Unless the Board determines otherwise, the stock purchase agreement or stock bonus agreement shall grant the Company a repurchase option exercisable upon the voluntary or involuntary termination of the Purchaser's employment with the Company for any reason (including death or disability). If the Board so determines, the purchase price for shares repurchased may be paid by cancellation of any indebtedness of the Purchaser to the Company. The repurchase option shall lapse at such rate as the Board may determine.
- d. <u>Other Provisions</u>. The stock purchase agreement or stock bonus agreement shall contain such other terms, provisions and conditions not inconsistent with the Plan as may be determined by the Board of Directors.
- 11. Non-Transferability of Options and Stock Purchase Rights. Unless determined otherwise by the Administrator, an Option or Stock Purchase Right may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the Optionee, only by the Optionee. If the Administrator makes an Option or Stock Purchase Right transferable, such Option or Stock Purchase Right shall contain such additional terms and conditions as the Administrator deems appropriate.

# 12. Adjustments upon Changes in Capitalization or Merger.

- a. Changes in Capitalization. Subject to any required action by the shareholders of the Company, the number of shares of Common Stock covered by each outstanding Option or Stock Purchase Right, and the number of shares of Common Stock which have been authorized for issuance under the Plan but as to which no Options or Stock Purchase Rights have yet been granted or which have been returned to the Plan upon cancellation or expiration of an Option or Stock Purchase Right, as well as the price per share of Common Stock covered by each such outstanding Option or Stock Purchase Right, shall be proportionately adjusted for any increase or decrease in the number of issued shares of Common Stock resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the Common Stock, or any other increase or decrease in the number of issued shares of Common Stock effected without receipt of consideration by the Company. The conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." Such adjustment shall be made by the Board, whose determination in that respect shall be final, binding and conclusive. Except as expressly provided herein, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number or price of shares of Common Stock subject to an Option or Stock Purchase Right.
- b. <u>Dissolution or Liquidation</u>. In the event of the proposed dissolution or liquidation of the Company, the Administrator shall notify the Optionee or Purchaser at least fifteen (15) days prior to such proposed action. To the extent it has not been previously exercised, the Option or Stock Purchase Right shall terminate immediately prior to the consummation of such proposed action.
- C. <u>Merger or Asset Sale</u>. In the event of a merger, sale of all or substantially all of the assets of the Company, tender offer or other transaction or series of related transactions resulting in a change of ownership of more than fifty percent (50%) of the voting securities of the Company ("Change

in Control"), approved by the majority of the members of the Board on the Board prior to the commencement of such Change in Control, each outstanding Option shall be assumed or an equivalent option or right substituted by the successor corporation or a Parent or Subsidiary of the successor corporation; provided however, in the event that within one year of the date of the completion of the Change in Control, the successor corporation or a Parent or Subsidiary of the successor corporation terminates the employment of an Optionee without Cause (as defined below), such Optionee shall fully vest in and have the right to exercise the options assumed or substituted for the Option as to all of the Optioned Stock, including Shares as to which it would not otherwise be exercisable. In the event that the successor corporation refuses to assume or substitute for the Option, the Optionee shall fully vest in and have the right to exercise the Option as to all of the Optioned Stock, including Shares as to which it would not otherwise be exercisable. If an Option becomes fully vested and exercisable in lieu of assumption or substitution in the event of a Change of Control, the Administrator shall notify the Optionee in writing or electronically that the Option shall be fully vested and exercisable for a period of fifteen (15) days from the date of such notice, and the Option shall terminate upon the expiration of such period. For the purposes of this paragraph, the Option shall be considered assumed if, following the Change of Control, the option confers the right to purchase, for each Share of Optioned Stock subject to the Option immediately prior to the Change in Control, the consideration (whether stock, cash, or other securities or property) received in the Change of Control by holders of Common Stock for each Share held on the effective date of the transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares); provided, however, that if such consideration received in the Change of Control is not solely common stock of the successor corporation or its Parent, the Administrator may, with the consent of the successor corporation, provide for the consideration to be received upon the exercise of the Option, for each Share of Optioned Stock subject to the Option, to be solely common stock of the successor corporation or its Parent equal in fair market value to the per share consideration received by holders of Common Stock in the Change of Control. For purposes of this paragraph, termination shall be for "Cause" in the event of the occurrence of any of the following: (a) any intentional action or intentional failure to act by employee which was performed in bad faith and to the material detriment of the successor corporation or its Parent or Subsidiary; (b) employee willfully and habitually neglects the duties of employment; or (c) employee is convicted of a felony crime involving moral turpitude, provided that in the event that any of the foregoing events is capable of being cured, the successor corporation or its Parent or Subsidiary shall provide written notice to the employee describing the nature of such event and the employee shall thereafter have five (5) business days to cure such event.

In the event of a Change in Control which is not approved by the majority of the members of the Board on the Board prior to the commencement of a Change in Control, each Optionee shall fully vest in and have the right to exercise all outstanding Options as to all of the Optioned Stock, including Shares as to which it would not otherwise be exercisable.

13. <u>Date of Granting Options</u>. The date of grant of an Option or Stock Purchase Right shall, for all purposes, be the date on which the Board makes the determination granting such Option or stock Purchase Right. Notice of the determination shall be given to each Employee or Consultant to whom an Option or Stock Purchase Right is so granted within a reasonable time after the date of such grant.

#### 14. Amendment and Termination of the Plan.

- a. <u>Amendment and Termination</u>. The Administrator may at any time amend, alter, suspend or discontinue the Plan, but no amendment, alteration, suspension or discontinuation shall be made which would impair the rights of any Optionee under any grant theretofore made, without his or her consent. In addition, to the extent necessary and desirable to comply with Section 422 of the Code (or any other applicable laws or regulation, the requirements of the NASD or an established Stock exchange), the Company shall obtain shareholder approval of any Plan amendment in such a manner and to such a degree as required.
- b. Effect of Amendment or Termination. Any such amendment or termination of the Plan shall not affect Options or Stock Purchase Rights already granted, and such Options and Stock Purchase Rights shall remain in full force and effect as if this Plan had not been amended or terminated, unless mutually agreed otherwise between the Optionee and the Administrator, which agreement must be in writing and signed by the Optionee and the Company.
- 15. <u>Conditions Upon Issuance of Shares</u>. Shares shall not be issued pursuant to the exercise of an Option or Stock Purchase Rights unless the exercise of such Option or Stock Purchase Rights and the issuance and delivery of such Shares pursuant thereto shall comply with all relevant provisions of law, including, without limitation, the Securities Act of 1933, as amended, the Exchange Act, the rules and regulations promulgated thereunder, and the requirements of any stock exchange upon which the Shares may then be listed, and shall be further subject to the approval of counsel for the Company with respect to such compliance.

As a condition to the exercise of an Option or Stock Purchase Right, the Company may require the person exercising such Option or Stock Purchase Right to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required by any of the aforementioned relevant provisions of law.

- 16. **Reservation of Shares.** The Company, during the term of this Plan, will at all times reserve and keep available such number of Shares as shall be sufficient to satisfy the requirements of the Plan. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority shall not have been obtained.
- 17. Option, Stock Purchase and Stock Bonus Agreements. Options shall be evidenced by written option agreements in such form as the Board shall approve. Upon the exercise of Stock Purchase Rights, the Purchaser shall sign a stock purchase agreement or stock bonus agreement in such form as the Board shall approve.
- 18. <u>Information to Optionees and Purchasers</u>. The Company shall provide to each Optionee and Purchaser, during the period for which such Optionee or Purchaser has one or more Options to Stock Purchase Rights outstanding, a balance sheet and an income statement at least annually. The Company shall not be required to provide such information to key employees whose duties in connection with the Company assure there access to equivalent information.

CERTAIN MATERIAL (INDICATED BY AN ASTERISK) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT 10.1

#### RESTRUCTURING AGREEMENT

Dated

September 30, 2002

**BETWEEN** 

TAISHO PHARMACEUTICAL CO., LTD.

AND

# NEUROCRINE BIOSCIENCES, INC.

This Agreement (this "Agreement"), dated September 30, 2002, is by and between Taisho Pharmaceutical Co., Ltd., a Corporation organized under the laws of Japan with principal offices located at 24-1, Takata 3-Chome, Toshima-ku, Tokyo 170-8633, Japan ("Taisho") and Neurocrine Biosciences, Inc., a Delaware Corporation with principal offices located at 10555 Science Center Drive, San Diego, California 92121 ("Neurocrine").

#### WITNESSETH:

**WHEREAS**, Neurocrine and Taisho entered into the License Agreement dated on July 21, 2000, amended by Amendment Number One dated on November 30, 2000 and Amendment letter dated April 10, 2002 ("License Agreement").

WHEREAS, Neurocrine and Taisho hoped to restructure the collaborative relationship under the License Agreement to secure all rights of Products and to commercialize Products with potential new partner ("New Partner" as defined below), and Neurocrine and Taisho entered into Amendment letter dated April 10, 2002

**WHEREAS**, Neurocrine and Taisho has reached agreement to restructure the collaborative relationship and amend the License Agreement to provide such restructuring.

**NOW THEREFORE**, in consideration of the foregoing and the covenants and promises contained in this Agreement, the parties agree as follows:

- 1. <u>Definitions</u>. Unless otherwise defined in this Agreement, capitalized terms used in this Agreement shall have the meanings assigned to such terms in the License Agreement.
- 2. Restructuring of Collaborative Relationship, Amendment to the License Agreement.
  - **2.1. Amendment of the Territory**. It is agreed that the License Agreement is hereby amended to provide that the Licensed Territory licensed to Taisho thereunder shall be limited to Japan and licenses for all other countries and territories revert to Neurocrine upon execution of this Agreement. Each party retains the rights to develop, manufacture and commercialize Products in their respective territories as is determined as above [\*\*\*].
  - **2.2. Limitation of Monetary Obligation, No Developmental Obligation.** It is agreed that Taisho shall be free from any and all monetary or developmental obligations past September 30, 2002 under the License Agreement, other than payment obligation for the remainder of Development Cost until September 30, 2002 ("Last Payment"). Neurocrine shall issue and send invoice of the Last Payment to Taisho no later than October 31, 2002. Taisho shall make the Last Payment within thirty (30) days of the receipt of such an invoice.
  - \*\*\* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

# 2.3 Profit Sharing.

- a. <u>Discussions</u>. On the date hereof, Taisho and Neurocrine are in discussion with [\*\*\*] and [\*\*\*] ([\*\*\*] and together with [\*\*\*], "New Partner") regarding a [\*\*\*] to NBI-6024. In the event neither New Partner has [\*\*\*] of the terms and conditions of such a [\*\*\*] on or before [\*\*\*], this Agreement will terminate upon [\*\*\*]. In the event one or both New Partners [\*\*\*] of the terms and conditions of such a [\*\*\*] on or before [\*\*\*], this Agreement will continue in full force and effect until [\*\*\*] or Neurocrine enters into a [\*\*\*] agreement with one of the New Partners. In the event a New Partner [\*\*\*], negotiation of the [\*\*\*] with that New Partner will be deemed terminated. If negotiations with both New Partners are [\*\*\*] this Agreement will terminate.
- b. <u>Consideration</u>. In the event business negotiations with a New Partner [\*\*\*] culminate in a [\*\*\*] agreement with the New Partner, in consideration of (i) Taisho's contribution for the Development under the License Agreement and Taisho's redelivery of all rights of Taisho to Products under the License Agreement and, (ii) Taisho's cooperation for restructuring the collaborative relationship between the parties and for seeking New Partner, Neurocrine shall pay to Taisho [\*\*\*] of the [\*\*\*] that are negotiated with the New Partner and Neurocrine would receive with respect to license of

NBI-6024 or Product(s). Neurocrine shall provide Taisho with a copy of agreement(s) or amendment(s) thereto executed by Neurocrine with the New Partner, to the extent necessary to confirm the payments Neurocrine would receive under such agreement. Payment to Taisho by Neurocrine shall be made (i) within thirty (30) days of receipt by Neurocrine of each such payment from the New Partner, (ii) by wire to the bank account designated by Taisho, (iii) in United States Dollars and (iv) under applicable tax treaty. The terms of any license agreement with a New Partner will be at Neurocrine's sole discretion and Neurocrine shall be under no obligation to accept any terms proposed by New Partner if Neurocrine determines it is not in its best interest.

#### 2.4 Term and Termination.

- a. This Agreement shall have effective period as the case may be as set forth in Section 2.3 (a) above. Provisions of Sections 3.2 and 3.3 hereof shall survive any termination of this Agreement. In addition, in case that this Agreement terminates upon Neurocrine's entering into a [\*\*\*] agreement with one the New Partners, provisions of Section 2.3 (b) hereof shall survive such termination.
- b. Termination of this Agreement shall terminate the License Agreement as amended by this Agreement and all rights and obligations of both parties thereunder unless otherwise stated herein. Provided, however, Article 1 and Section 13.13 in the License Agreement shall survive the termination of the License Agreement, and Article 10 in the License Agreement shall be effective until September 30, 2007. Taisho shall destroy any and all Confidential Information provided from Neurocrine under the License Agreement at its own cost, and Taisho shall notify Neurocrine of completion of the destruction immediately after such a completion.

\*\*\* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

#### 3. Miscellaneous.

- 3.1 Entire Agreement. This Agreement and the License Agreement constitute the entire agreement with respect to the subject matter hereof, and supersedes all prior or contemporaneous understandings or agreements, whether written or oral, between Neurocrine and Taisho with respect to such subject matter. Except as explicitly set forth in this Agreement, each of the parties hereto has no rights or obligations to the other party with respect to the License Agreement or subject matter thereof.
- **3.2 Dispute resolution**. Section 13.13 in the License Agreement shall also apply to this Agreement.

3.3 Press releases. Press releases and any form of publication regarding this Agreement shall be reviewed by the non-publishing party. Publishing party will submit a draft of press release or publish regarding this Agreement to non-publishing party for comments at least ten (10) business days prior to release or publication. Neither party will release any contents of this Agreement without consent of non-publishing party, not to be unreasonably withheld. Comments will be provided as soon as practicable, and in no event later than seven (7) business days after receipt thereof, after which consent shall be deemed given in the absence of a response.

**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be duly executed and delivered in duplicate originals as of the date first above written.

### TAISHO PHARMACEUTICAL CO., LTD.

By: /s/ KUNIHIRO KITAMURA

Name: Kunihiro Kitamura

Title: Executive Officer

Date: September 30, 2002

#### NEUROCRINE BIOSCIENCES, INC.

By: /s/ PAUL H. HAWRAN

Name: Paul H. Hawran

Title: Executive Vice President and Chief Financial Officer

Date: September 25, 2002