SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of the earliest event reported): April 29, 2003

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware

0-28150

(State or other jurisdiction of incorporation or organization)

(Commission File Number)

33-0525145 (IRS Employer Identification No.)

10555 Science Center Drive, San Diego, CA (Address of principal executive offices) **92121** (Zip Code)

Registrant's telephone number, including area code: (858) 658-7600

N/A

(Former name or former address, if changed since last report.)

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.

(c) EXHIBITS. The following exhibits are filed herewith:

ExhibitNumberDescription of Exhibit99.1Press Release dated April 29, 2003

ITEM 9. REGULATION FD DISCLOSURE (INFORMATION FURNISHED IN THIS ITEM 9 IS FURNISHED UNDER ITEM 12).

On April 29, 2003, Neurocrine Biosciences, Inc. announced its financial results for the quarter ended March 31, 2003. The full text of the press release issued in connection with the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K.

This Form 8-K and the attached exhibit are being furnished pursuant to Item 12 of Form 8-K ("Disclosure of Results of Operations and Financial Condition") in accordance with the interim guidance provided by the Securities and Exchange Commission pursuant to SEC Releases Nos. 33-8216; 34-47583, insofar as they disclose historical information regarding the Registrant's results of operations or financial condition for the quarter ended March 31, 2003. The information in this Current Report of Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

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: April 29, 2003

NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN

Paul W. Hawran

Executive Vice President and Chief Financial Officer

NEUROCRINE BIOSCIENCES REPORTS FIRST QUARTER 2003 RESULTS

The Company also Announces the Inlicensing of a Phase II Compound from Pharmacia (Now Pfizer) for Erectile Dysfunction

San Diego, CA, April 29, 2003 - Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended March 31, 2003. For the first quarter, the Company reported a net loss of \$13.4 million, or \$0.43 per share compared with a net loss of \$15.8 million or \$0.52 per share for the same period last year.

Revenues for the first quarter of 2003 were \$37.7 million compared with \$5.0 million for the same period last year. The net increase in revenues of \$32.7 million primarily resulted from revenues recognized under the Pfizer, Inc. (Pfizer) collaborative agreement that was finalized in December 2002. During the first three months of 2003, the Company recognized \$34.4 million in revenue under the Pfizer agreement. Revenue totaling \$1.8 million was also recognized under the ongoing collaborative agreement with GlaxoSmithKline for the three months of 2003, compared to \$1.9 million in revenue for the same period in 2002.

Research and development expenses increased to \$48.3 million for the first quarter 2003 compared with \$20.0 million for the respective period in 2002. Increased expenses primarily reflect higher costs associated with expanding clinical and commercialization activities for the *indiplon* Phase III program and expansion of the Company's research activities. General and administrative expenses increased to \$4.7 million for the first quarter 2003 compared with \$2.7 million during the same period last year. Increased general and administrative expenses relate to increased support of research and development efforts, marketing and market research costs, and increased business development activity.

The Company's balance sheet on March 31, 2003 reflected total assets of \$363.0 million, including cash, cash equivalents, marketable securities and current receivables of \$338.0 million compared with balances at December 31, 2002 of \$266.5 million and \$245.0 million, respectively. The increase in cash, cash equivalents, marketable securities and current receivables is a result of the initial \$100 million payment and funding for the *indiplon* development program under the collaboration agreement with Pfizer.

"The financial results for the quarter were positively impacted by the satisfaction of the Hart Scott Rodino (HSR) requirements and subsequent payment of \$100 million by Pfizer. Our financial condition continues to be strengthened with net cash outlays being notably reduced as a result of the Pfizer collaboration," said Paul W. Hawran, Executive Vice President and Chief Financial Officer of Neurocrine Biosciences. "We continue to advance our Phase III *indiplon* program through the final phase of development toward commercialization, and are encouraged by the positive results demonstrated to date. We remain on track to file our New Drug Application (NDA) for *indiplon* in early 2004. In addition, we are pleased to announce the inlicensing of a Phase II compound for erectile dysfunction (ED) from Pharmacia Corp. as a condition of Pharmacia's merger with Pfizer. We expect to conduct a Phase II proof of concept clinical trial this year," added Hawran.

Clinical Program Update

The *indiplon* development program is one of the most extensive clinical programs conducted to date addressing the multiple needs of adult and elderly adult patients with insomnia such as sleep initiation, sleep maintenance and long-term administration. The studies of both immediate release and modified release formulations have included over 3,000 adult and elderly subjects and patients and have demonstrated positive results in both efficacy and safety. In addition, *indiplon* has consistently shown no next day residual effects across all trials using all three validated measurements (Visual Analogue Scale (VAS), Digit Symbol Substitution Test (DSST) and Symbol Copy Test (SCT) as compared to both placebo and baseline. The Company has completed and reported on two of eight Phase III clinical trials. The remaining trials are currently in progress with results expected later this year.

<u>Indiplon</u>

<u>Completed Phase III Trial Results with the Immediate Release Formulation:</u>

- <u>Transient Insomnia</u> A study in 593 adult subjects assessed the efficacy and safety of the immediate release formulation of *indiplon* with the primary endpoint of Latency to Persistent Sleep (LPS) with a secondary endpoint of Latency to Sleep Onset (LSO). This study was concluded in 2002 with results demonstrating that *indiplon* achieved rapid sleep induction without next day residual effects and was safe and well tolerated. The immediate release formulation showed a statistically significant improvement in the primary endpoint of LPS at both dose levels relative to placebo.
- <u>Thirty-Five Day Efficacy and Safety Trial in Chronic Primary Insomnia</u> The second Phase III trial evaluated two dose levels of *indiplon* vs. placebo in 200 adult patients and was concluded earlier this month. The trial showed statistically significant results in both primary and secondary endpoints of sleep initiation with no evidence of next day residual effects. Also, *indiplon* was safe, well tolerated and effective throughout the treatment period showing no indication of tolerance.

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Ongoing Phase III Trials with the Immediate Release Formulation of indiplon:

- <u>One Year Safety Study in Patients with Chronic Primary Insomnia</u> Enrollment has been completed and of the 536 patients randomized to receive one of two doses of *indiplon* for twelve months, approximately 150 subjects have completed the trial through the first quarter 2003. The Company expects the last patient dosing to be completed in June with results expected to be released shortly thereafter.
- Long Term Efficacy and Safety in Adult Patients with Chronic Primary Insomnia Enrollment is nearing completion in a three to six-month Phase III study of two indiplon doses in approximately 600 patients (the "RESTFUL" trial). The primary endpoint for this study is Latency to Sleep Onset (LSO) as measured by patient self reported outcomes. The results are expected to be announced later this year.

<u>Two Week Efficacy and Safety in Elderly Patients with Chronic Primary Insomnia</u> – Enrollment is more than 50% complete in the trial which is
assessing the efficacy and safety of two dose levels of *indiplon* in approximately 360 elderly patients with Chronic Primary Insomnia. The primary
endpoint for this study is LSO as measured by patient self reported outcomes. The results of the two-week period evaluation are expected to be
announced later this year.

Ongoing Phase III Trials of the Modified Release Formulation of indiplon:

- <u>Long Term Efficacy and Safety in Adults with Chronic Primary Insomnia</u> Enrollment is approximately 75% complete in this long-term three to six month study (the "SLEEP" trial) assessing two *indiplon* dose levels relative to placebo in approximately 600 patients with Sleep Maintenance Insomnia. The results are expected to be announced later this year.
- <u>Thirty-Five Day Inpatient/Outpatient Efficacy and Safety in Elderly patients with Chronic Primary Insomnia</u> Enrollment is approximately 50% complete in this study involving two doses of *indiplon* versus placebo in 300 elderly patients. The Study will assess Sleep Maintenance. Results are expected to be announced later this year.
- <u>Two-week Efficacy and Safety in Elderly Patients with Chronic Primary Insomnia</u> –Enrollment is approximately 50% complete in this trial assessing efficacy and safety of *indiplon* in 220 elderly patients for Sleep Maintenance Insomnia. Results are expected to be announced later this year.

GnRH for Women's Health Disorders and Prostate Cancer

Neurocrine's GnRH (Gonadotropin-releasing hormone) compound successfully demonstrated reductions in luteinizing hormone production (a surrogate measure of efficacy) in a Phase I single dose safety clinical trial. Based on the positive results, the compound progressed to a one week multiple dose study in premenopausal women that has been completed. The results of this trial will be available late in the second quarter. A second generation GnRH candidate is expected to advance into human clinical trials in July with a third compound completing preclinical requirements later this year.

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D2 Receptor Agonist for Erectile Dysfunction

In the first quarter of 2003, Neurocrine acquired the rights from Pharmacia to develop indications related to male and female sexual dysfunction for PnU 142,774, a selective dopamine D2 receptor agonist. As a condition to the closing of the Pharmacia-Pfizer merger, the Federal Trade Commission required Pharmacia to divest PnU 142,774 to enhance competition in the market for human sexual dysfunction. The compound has demonstrated high intrinsic activity in animal models of sexual dysfunction, and Neurocrine will conduct a Phase II proof of concept clinical study in the area of erectile dysfunction (ED) this year in order to determine its potential efficacy. ED affects nearly 77 million men in the world's seven major pharmaceutical markets, and PDE-5 inhibitors such as Viagra are the only effective oral treatment. PnU 142,774 may offer a more selective mechanism of action and an improved product profile to this currently underserved market.

CRF for Stress Related Disorders

Under Neurocrine's CRF program with GlaxoSmithKline (GSK), the company has developed multiple compounds that are in various stages of research and preclinical development. Expanding Neurocrine's franchise in CRF, the company has licensed Urocortin II from the Clayton Foundation/Salk Institute. Urocortin II is a recently discovered endogenous peptide ligand of the CRF-R2 receptor. Neurocrine will be exploring the utility of this compound in endocrine, metabolic, and cardiovascular disorders.

Altered Peptide Ligand (APL) for Type I Diabetes and Multiple Sclerosis

The APL technology platform has resulted in two Phase II products, NBI-6024 for Type I Diabetes and NBI-5788 for Multiple Sclerosis. NBI-6024 for Type I Diabetes has successfully completed four Phase I/II clinical trials. The Company is currently conducting a Phase II, dose response, efficacy and safety trial in approximately 200 adult/adolescents. Enrollment is expected to be completed by year end and results reported in late 2004. The second APL product, NBI-5788 for Multiple Sclerosis is expected to begin a second Phase II efficacy and safety trial in the second quarter of 2003 with results expected in 2005.

IL4 for Glioblastoma and Peripheral Cancers

The IL-4 fusion toxin program for glioblastoma recently completed a Phase II trial. An earlier study had shown NBI-3001 to be safe with demonstrated antitumor effects in the majority of patients. The recently completed study was designed to explore an improved delivery regimen and to determine a safe and optimal dose for Phase III trials. The results of this trial indicate a safe and well-tolerated dose had been determined and that the compound is now ready to enter advanced efficacy trials using survival as the valid endpoint. Neurocrine has submitted a publication which has been accepted and will be published in the Journal of Neuro-Oncology later this year. The Company also successfully completed a Phase I safety study in kidney and lung cancer patients. The Company believes the compound is better suited for development by an oncology-focused company, and is currently pursuing out-licensing opportunities.

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Neurocrine Biosciences, Inc. is a product-based biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including insomnia, anxiety, depression, diabetes, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, autoimmunity and certain female and male health disorders. Neurocrine Biosciences, Inc. news releases are available through the Company's website via the Internet at http://www.neurocrine.com.

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward looking statements are risks and uncertainties associated with Neurocrine's development programs and business and finances including, but not limited to, risk that Neurocrine's drug candidates will not successfully proceed through clinical trials or that later stage clinical trials will not show that they are effective in treating humans; determinations by regulatory and governmental authorities; dependence on corporate collaborators who could terminate their relationships with the Company at any time; uncertainties relating to patent protection and intellectual property rights of third parties; impact of competitive products and technological changes; availability of capital and cost of capital; and other material risks. A more complete description of these risks can be found in the Company's Form 10K for the year ended December 31, 2002 and the

current form 10Q each of which should be read before making any investment in Neurocrine common stock. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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NEUROCRINE BIOSCIENCES, INC.

Condensed Statements of Operations (in thousands, except for loss per share data)

Three Months Ended March 31, 2003 2002 (unaudited) (unaudited) Revenues: Sponsored research and development \$ 30,725 \$ 3,958 License fees 6,667 583 Grant income 324 416 Total revenues 4,957 37,716 Operating expenses: Research and development 48,324 20,047 General and administrative 4,744 2,731 Total operating expenses 53,068 22,778 Loss from operations (15,352) (17,821) Other income and (expenses): Interest income and other income, net 2,065 1,944 Other income, net 48 113 Loss before income tax expense (13, 239)(15,764)Income tax expense 151 (13,390) Net loss \$ \$ (15,764)Loss per common share: \$ Basic and Diluted (0.43)\$ (0.52)Shares used in the calculation of loss per common share: Basic and Diluted 30,789 30,384

NEUROCRINE BIOSCIENCES, INC.

Condensed Balance Sheets (in thousands)

		March 31, 2003		December 31, 2002	
	(unau	udited)			
Cash, cash equivalents and marketable securities	\$	308,239	\$	244,710	
Other current assets		33,570		3,384	
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Total current assets		341,809		248,094	
Property and equipment, net		14,372		14,102	
Other non-current assets		6,863		4,343	
Total assets	\$	363,044	\$	266,539	
Current liabilities	\$	97,085	\$	32,479	
Long-term liabilities		50,746		9,806	
Stockholders' equity		215,213		224,254	

Total liabilities and stockholders' equity	\$ 363,044	\$ 266,539