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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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): July 24, 2003

**NEUROCRINE BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>0-28150</b> (Commission File Number)	<b>33-0525145</b> (IRS Employer Identification No.)
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<b>10555 Science Center Drive, San Diego, CA</b> (Address of principal executive offices)	<b>92121</b> (Zip Code)
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Registrant's telephone number, including area code: **(858) 658-7600**

**N/A**

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

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**ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.**

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

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	Press Release dated July 24, 2003

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

On July 24, 2003, Neurocrine Biosciences, Inc. announced its financial results for the quarter ended June 30, 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 June 30, 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: July 24, 2003

NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN

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Paul W. Hawran



**FOR IMMEDIATE RELEASE**

Contact at Neurocrine Biosciences  
 Claudia Jones or Elizabeth Foster  
 (858) 658-7600

**NEUROCRINE BIOSCIENCES REPORTS SECOND QUARTER 2003 RESULTS****THE COMPANY ALSO ANNOUNCES PRELIMINARY RESULTS OF THE ONE YEAR PHASE III SAFETY STUDY WITH INDIPLON AND PROVIDES OVERALL CLINICAL DEVELOPMENT UPDATE**

San Diego, CA, July 24, 2003 - Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended June 30, 2003. For the 2nd quarter, the Company reported a net loss of \$10.2 million, or \$0.33 per share compared with a net loss of \$19.8 million or \$0.65 per share for the same period last year. For the six months, the Company reported a net loss of \$23.6 million as compared to \$35.5 million in the same period last year.

Revenues for the 2nd quarter of 2003 were \$45.0 million compared with \$4.2 million for the same period last year. Revenues for the six months ended June 30, 2003, were \$82.7 million, compared with \$9.2 million for the same period in 2002. The increase in revenues for the three and six months ended June 30, 2003 resulted primarily from reimbursement of clinical development expenses associated with the indiplon program under the Pfizer collaboration of \$31.9 million and \$61.2 million, respectively. In addition, the Company recognized \$11.0 million and \$16.1 million, respectively in license fee revenues arising from the Pfizer collaboration.

Research and development expenses increased to \$52.3 million for the 2nd quarter 2003 compared with \$23.1 million for the respective period in 2002. For the six months ended June 30, 2003, research and development expenses were \$100.6 million compared to \$43.1 million for the same period last year. Increased expenses primarily reflect higher costs associated with expanding development activities, particularly the indiplon Phase III program (for insomnia). The Company currently has 17 programs in various stages of research and development, including seven programs in clinical development. Additionally, personnel and laboratory costs related to the expansion of research activities have increased during the same period. General and administrative expenses increased to \$5.1 million for the 2nd quarter 2003 compared with \$3.2 million for the same period last year. For the six months ended June 30, 2003 general and administrative expenditures totaled \$9.9 million compared to \$5.9 million in 2002. The increased cost resulted primarily from increased market research and marketing related costs, increased professional fees associated with business development, increased insurance costs, and the addition of administrative personnel needed to support expanding research and development activities.

The Company's balance sheet on June 30, 2003 reflected total assets of \$372.8 million, including cash, cash equivalents, marketable securities and current receivables of \$305.0 million compared with balances at December 31, 2002 of \$266.5 million and \$245.0 million, respectively. The increase in cash balances at June 30, 2003 resulted primarily from the receipt of the initial license and collaboration payments from Pfizer totaling \$100.0 million, offset by capital acquisitions and operating losses.

During the 2nd quarter the Company, in anticipation of new accounting requirements, which take effect in the 3rd quarter 2003, consolidated Science Park LLC, a company created in 1997 to purchase the Company's existing research and administrative building. Accordingly, the Company recorded the carrying value of the building and related long term debt of approximately \$14 million. In addition, during the 2nd quarter 2003, the Company entered into an agreement to sell the existing building and adjacent land for \$40 million to an unrelated third party. The Company, through Science Park LLC, also has entered into an agreement to purchase approximately 14 acres of undeveloped land nearby the existing facility. The Company intends to develop and build a new corporate facility which is expected to be completed mid-year 2004 for an estimated cost of \$60 million. The new facility will be funded through the net proceeds of the existing facility and long term mortgage debt. In conjunction with the sale of the existing facility, the Company expects to record a one time gain of approximately \$18 million in the 4th quarter 2003.

**Clinical Program Update****Indiplon Clinical Trial Program Advances**

Neurocrine is conducting one of the most comprehensive clinical programs in insomnia to address the multiple needs of younger and older adult patients with insomnia such as sleep initiation, sleep maintenance, and long-term administration. The Company has completed more than 40 clinical trials demonstrating safety and efficacy of indiplon in treating patients with Transient as well as Chronic Primary Insomnia. Trial results demonstrate that clinically relevant doses of indiplon consistently show no evidence of next day residual effects across all trials compared to both placebo and baseline using all three validated measurements. These measurements include the Digit Symbol Substitution Test (DSST) and Symbol Copy Test (SCT), Visual Analogue Scale (VAS) for sleepiness.

To date, Neurocrine has enrolled over 5,700 patients in the indiplon clinical trial program; enrollment in existing trials will be complete by the 3rd quarter. The Company anticipates announcing results of the remaining Phase III trials in late 3rd quarter and continuing through the 1st quarter 2004.

In addition, Pfizer and Neurocrine have recently increased the indiplon development program budget to optimize the NDA submission. A portion of this will be paid by Neurocrine during 2003 and 2004. The clinical trial endpoints have not been changed or modified nor have any interim analyses been performed.

The Company is also working with the Food and Drug Administration to schedule a pre-NDA meeting in 3rd quarter and anticipates filing an NDA for indiplon in the first half of 2004.

Below is a summary of ongoing Phase III clinical trials in both the immediate and modified release formulations of indiplon:

**RECENTLY COMPLETED CLINICAL TRIALS FOR INDIPLON IMMEDIATE AND MODIFIED RELEASE FORMULATIONS****One Year Safety Study**

Neurocrine Biosciences, Inc. also announces today the completion of the Company's one-year safety clinical trial with the immediate release formulation of indiplon in adult patients with Chronic Primary Insomnia. Based on preliminary observation of data collected this study demonstrates that indiplon was safe and well tolerated. These safety results were consistent with previous trial results.

The study was a randomized, double-blind, multi-center Phase III clinical trial designed to assess the safety of Long-Term Administration of two dose levels (20 mg and 10 mg) of immediate release indiplon capsules in adult patients with Chronic Primary Insomnia. Patients were randomized to receive either 20 mg or 10 mg of indiplon in a 2:1 ratio. A total of 536 patients were randomized and 211 patients completed one year of dosing (target: 100 patients) with indiplon. Safety assessments were conducted at baseline and at periodic visits during the treatment period and on the final day study visit.

Data from this study is expected to satisfy the requirements for long-term safety exposure recommended by current International Conference on Harmonization (ICH) guidance and required by the Food and Drug Administration.

Preliminary observation of data collected in this study indicate that indiplon was safe and well tolerated. These safety results were consistent with previous trial results.

**Two-week Efficacy and Safety Clinical Trial in Adult Patients with Chronic Primary Insomnia** - Enrollment has been completed in this randomized, double-blind, placebo-controlled outpatient study designed to assess the efficacy and safety of the modified release formulation of indiplon 30 mg relative to placebo in adult primary insomnia patients with sleep maintenance difficulty following two weeks of drug administration. The primary endpoint for this study is patient reported Total Sleep Time (sTST). A total of 210 patients were enrolled from 32 sites in the U.S. and results are expected to be announced in 3rd quarter 2003.

**Six month Safety & Efficacy Extension Trial** Neurocrine has completed enrollment in a Phase III extension clinical study with 121 elderly patients who are continuing evaluation with the immediate release formulation of indiplon after completing the two week safety and efficacy Phase III clinical trial. Patients in the extension study will take open label indiplon 5 mg or 10 mg dose for 6 months. The purpose of the study is to obtain long-term safety exposure data recommended by current ICH guidance to satisfy regulatory requirements. Results from this study are expected to be available shortly.

**Middle of the Night (MOTN) Dosing in Adult Patients with Chronic Primary Insomnia** Enrollment has been completed in this randomized, placebo-controlled, double-blind, parallel group. The primary goal of the study was to assess the efficacy of indiplon relative to placebo after MOTN administration in patients characterized by MOTN awakening with difficulty getting back to sleep. Secondary goals included the assessment of safety and tolerability, and next morning residual effects of indiplon relative to placebo after MOTN administration. A total of 264 patients were enrolled from 15 sites across the U.S. Results from this study are expected to be available in the 4th quarter.

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

**Long Term Efficacy and Safety in Adult Patients with Chronic Primary Insomnia (the "Restful" Trial)** - The Company has reported that the majority of patients have been enrolled in this 3/6 month trial which was initially designed to enroll 600 patients but has been expanded to include approximately 700 patients to ensure the robustness of the data sets and the trial's success. The primary endpoint is Latency to Sleep Onset (LSO) as measured by patient self reported outcomes. Results are expected to be announced in early 2004.

**Two Week Efficacy and Safety in Elderly Patients with Chronic Primary Insomnia** - Enrollment in this two week elderly trial is expected to be completed in the 3rd quarter. The trial 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. Results are expected to be announced by year end 2003.

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

**Long Term Efficacy and Safety in Adults with Chronic Primary Insomnia (the "Sleep" Trial)** - This 3/6 month trial has also been increased from 600 patients to approximately 700 patients and is anticipated to complete enrollment by the end of the 3rd quarter. This three month study assesses two indiplon dose levels relative to placebo in patients with Sleep Maintenance Insomnia. The primary endpoint for this study is patient reported Total Sleep Time (sTST). Results are expected to be announced in early 1st quarter 2004.

**Thirty-Five Day Inpatient/Outpatient Efficacy and Safety Clinical Trial in Elderly Patients with Chronic Primary Insomnia** - The Company has enrolled over 200 patients in this study involving two doses of indiplon versus placebo in 300 elderly patients. The study will assess Sleep Maintenance. The primary endpoint for this study is Wake After Sleep Onset (WASO) as measured by polysomnography (PSG). Results are expected to be announced in early 2004.

**Two-week Efficacy and Safety Clinical Trial in Elderly Patients with Chronic Primary Insomnia** - Enrollment is expected to complete in the 3rd quarter. This trial is assessing the efficacy and safety of indiplon in 220 elderly patients with Sleep Maintenance Insomnia. The primary endpoint for this study is patient reported Total Sleep Time (sTST). Results are expected to be announced in January 2004.

#### **GnRH for Women's Health Disorders and Prostate Cancer**

Neurocrine recently announced positive results in a second Phase I trial for the proprietary, orally active small molecule GnRH (Gonadotropin-releasing Hormone) receptor antagonist. This study evaluated the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of multiple-dosing of NBI-42902 in healthy pre-menopausal women. The preliminary pharmacokinetic data demonstrated that NBI-42902 was absorbed rapidly after oral administration. The systemic exposure was proportional to the total dose given either once-a-day or twice-a-day and was similar between day one and day seven of dosing indicating no evidence of accumulation, enzyme induction or inhibition. Initial pharmacodynamic evaluation indicated suppression of luteinizing hormone (LH) as expected based on data from a previous study with NBI-42902 in postmenopausal women. In addition, gonadal suppression was achieved in five out of six women in the twice-a-day dose group resulting in suppression of estrogen to levels expected to be therapeutic. NBI-42902 was well tolerated by all subjects with no discontinuations or serious adverse events. A second generation GnRH candidate is expected to advance into human clinical trials in September with a third compound completing preclinical requirements later this year.

In addition, the Company announced that Dr. Sam Yen has joined the Company as Distinguished Clinical Scientist. In his role Dr. Yen will direct the GnRH program. Prior to joining Neurocrine, Dr. Yen established and was Chairman of the Department of Reproductive Medicine at University of California San Diego (UCSD) and was the Director of the NIH Center for Reproductive Sciences at UCSD. Dr. Yen continues as Professor Emeritus at UCSD. Dr. Yen brings more than four decades of experience as a pioneer and international leader in the field of clinical reproductive endocrinology and neuroendocrinology. Dr. Yen has received numerous awards, published approximately 500 research papers and is credited as writing the authoritative textbook on reproductive endocrinology.

#### **D2 Receptor Agonist for Erectile Dysfunction**

Neurocrine acquired the rights to develop indications related to male and female sexual dysfunction for NBI-69733, from Pharmacia, a selective dopamine D2 receptor agonist, in the 1st quarter of 2003. The compound has demonstrated high intrinsic activity in animal models of sexual dysfunction. Neurocrine will conduct a Phase II proof of concept clinical study in the area of male erectile dysfunction (ED) early next 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. NBI-69733 may offer a more selective mechanism of action and an improved product profile to this currently underserved market.

### **CRF for Stress Related Disorders**

Neurocrine's CRF program with GlaxoSmithKline (GSK) has developed multiple compounds that are in various stages of research and preclinical development. The Company has licensed Urocortin II from the Clayton Foundation/Salk Institute to further expand Neurocrine's franchise in CRF. 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 and is expected to enter Phase I trials in early 2004.

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

Neurocrine has advanced two APL products into Phase II clinical development, 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 in the 1st quarter 2004 with preliminary results expected in late 2005. The Company will also initiate a Phase II clinical trial with NBI-5788 in patients with relapsing multiple sclerosis shortly.

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 may contain 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 business and finances and research programs in general including, but not limited to, risk and uncertainties associated with, or arising out of, drug discovery, pre-clinical and clinical development of products including risk that the Company's UII research program will not lead to a clinical candidate, that the CRF, D2 receptor agonist and altered peptide ligand clinical candidates will not proceed to later stage clinical trials and risks and uncertainties associated with the Company's indiplon Phase III program and planned regulatory activities. Specifically, the risks and uncertainties the Company faces with respect to its indiplon program include, but are not limited to, risk that indiplon may not successfully proceed through Phase III clinical trials or Phase III clinical trials may fail to demonstrate that indiplon is safe and effective in treating humans; risk that the Company may not complete indiplon Phase III clinical trials on the Company's projected timelines for various reasons, including the possibility that patient recruitment may be slower than expected; risk that the clinical investigators and contract research organizations upon which the Company relies to conduct its clinical programs may not be diligent, careful or timely, and may make mistakes, in the conduct of the programs; risk relating to the Company's dependence on contract manufacturers for clinical drug supply and compliance with regulatory requirements for marketing approval; risk that the Company may not successfully co-ordinate the completion and submission of planned regulatory filings on the Company's projected timelines; risk that the Company may not receive regulatory approval for indiplon or approval may be delayed; risks associated with the Company's dependence on corporate collaborators for commercial manufacturing and marketing and sales activities; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products; risk that the Company will be unable to raise additional funding required to complete development of all of its product candidates; and the other risks described in the Company's Form 10-K for the year ended December 31, 2002 and the Company's most recent report on Form 10-Q. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.*

## **NEUROCRINE BIOSCIENCES, INC.**

### **Condensed Consolidated Statements of Operations**

**(in thousands, except for loss per share data)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2003</b>	<b>2002</b>	<b>2003</b>	<b>2002</b>
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
<b>Revenues:</b>				
Sponsored research and development	\$ 33,346	\$ 3,180	\$ 64,071	\$ 7,138
License fees	11,320	583	17,987	1,166
Grant income	302	464	626	880
<b>Total revenues</b>	<b>44,968</b>	<b>4,227</b>	<b>82,684</b>	<b>9,184</b>
<b>Operating expenses:</b>				
Research and development	52,323	23,096	100,647	43,143
General and administrative	5,135	3,151	9,879	5,882
<b>Total operating expenses</b>	<b>57,458</b>	<b>26,247</b>	<b>110,526</b>	<b>49,025</b>
<b>Loss from operations</b>	<b>(12,490)</b>	<b>(22,020)</b>	<b>(27,842)</b>	<b>(39,841)</b>
<b>Other income and (expenses):</b>				
Interest income and expense, net	2,211	2,191	4,276	4,135
Other income and expense, net	54	78	(49)	191
<b>Total other income and (expenses)</b>	<b>2,265</b>	<b>2,269</b>	<b>4,227</b>	<b>4,326</b>

Net loss	\$	(10,225)	\$	(19,751)	\$	(23,615)	\$	(35,515)
Net loss per common share:								
Basic and Diluted	\$	(0.33)	\$	(0.65)	\$	(0.76)	\$	(1.17)
Shares used in the calculation of net loss per common share:								
Basic and Diluted		31,334		30,433		31,063		30,408

**NEUROCRINE BIOSCIENCES, INC.**  
**Condensed Consolidated Balance Sheets**  
(in thousands)

	June 30, 2003	December 31, 2002
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 272,814	\$ 244,710
Other current assets	41,484	3,384
Total current assets	314,298	248,094
Property and equipment, net	48,407	14,102
Other non-current assets	10,057	4,343
Total assets	\$ 372,762	\$ 266,539
Current liabilities	\$ 101,612	\$ 32,479
Long-term liabilities	61,181	9,806
Stockholders' equity	209,969	224,254
Total liabilities and stockholders' equity	\$ 372,762	\$ 266,539