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): July 28, 2004

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware 0-28150 33-0525145

(State or other jurisdiction of incorporation or organization)

(Commission File Number) (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) 617-7600

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:

Exhibit

Number Description of Exhibit

99.1 Press Release dated July 28, 2004

ITEM 12. RESULTS OF OPERATION AND FINANCIAL CONDITION

On July 28, 2004, Neurocrine Biosciences, Inc. announced its financial results for the quarter ended June 30, 2004. 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.

In accordance with General Instruction B.6. of Form 8-K, 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, as amended, (the "Exchange Act") or otherwise subject to the liability 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 a 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 28, 2004 NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN

Paul W. Hawran
Executive Vice President

and Chief Financial Officer

FOR IMMEDIATERELEASE

Contact at Neurocrine Biosciences Elizabeth Foster or Claudia Jones (858) 617-7600

NEUROCRINE BIOSCIENCES REPORTS SECOND QUARTER 2004 RESULTS

NEUROCRINE RECEIVES MILESTONE FROM PFIZER FOR ACHIEVEMENT OF LONG TERM EFFICACY RESULTS WITH INDIPLON

San Diego, CA, July 28, 2004 - Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended June 30, 2004. For the second quarter, the Company reported a net loss of \$11.1 million, or \$0.31 per share compared with a net loss of \$10.2 million, or \$0.33 per share, for the same period last year. For the six months, the Company reported a net loss of \$23.5 million, or \$0.65 per share, as compared to \$23.6 million, or \$0.76 per share, for the same period last year.

Revenues for the second quarter of 2004 were \$15.0 million compared with \$45.0 million for the respective period last year. Revenues for the six months ended June 30, 2004 were \$32.0 million compared with \$82.7 million for the same period in 2003. The decrease in revenues for the three and six month period is primarily due to lower sponsored development revenue associated with the winding down of the *indiplon* registration clinical program, offset by increased license fees and milestones achieved under research and development collaborations. During 2004, the Company recognized \$1.1 million and \$5.1 million, for the three and six months ended June 30, 2004 in the form of sponsored development funding under the Pfizer collaboration agreement. During 2003, the Company recognized \$31.9 million and \$61.2 million, for the three and six months ended June 30, 2003 in the form of sponsored development funding under the Pfizer collaboration agreement. License fees and milestones recognized under the Pfizer collaboration were \$11.5 million and \$22.5 million for the three and six months ended June 30, 2004 and \$10.9 million and \$16.1 million for the three and six months ended June 30, 2003. During the second quarter of 2004, the Company achieved a \$3.0 million milestone under the Pfizer agreement related to the successful completion of Phase III clinical trial results for long-term administration of *indiplon*. In addition, the Company received a \$500,000 milestone payment from GlaxoSmithKline (GSK) related to the selection of a development candidate in our CRF research program.

Research and development expenses decreased to \$23.0 million for the second quarter of 2004 compared with \$52.3 million for the respective period in 2003. For the six months ended June 30, 2004, research and development expenses were \$49.4 million compared to \$100.6 million for the same period last year. Decreased expenses primarily reflect the winding down of our Phase III program for *indiplon*, offset by increased research and development expenses in other programs and increased personnel and laboratory costs.

General and administrative expenses increased to \$5.5 million for the second quarter of 2004 compared with \$5.1 million during the same period last year. For the six months ended June 30, 2004, general and administrative expenses were \$10.8 million compared to \$9.9 million for the respective period in 2003. The increase in expenses from 2003 to 2004 resulted primarily from the addition of administrative personnel to support the expanding research and development activities, marketing and business development.

The Company's balance sheet on June 30, 2004 reflected total assets of \$546.5 million, including cash, cash equivalents, marketable securities of \$326.5 million compared with balances at December 31, 2003 of \$555.0 million and \$453.2 million, respectively. The decrease in cash balances resulted primarily from the purchase of the indiplon royalty stream from Wyeth for \$50.0 million cash combined with a reduction in accounts payable related to clinical trials and the year-to-date operating loss.

"We are pleased to report that Neurocrine has accomplished an important clinical milestone with *indiplon* in treating chronic insomnia. Patients have been successfully treated with both the IR & MR formulations in three month studies with cohorts completing an additional three months of therapy," said Paul W. Hawran, Executive Vice President and Chief Financial Officer of Neurocrine Biosciences. "Our financial condition continues to be strong and we continue to manage at a controlled burn rate as we advance multiple new products into Phase I clinical trials this year and increase our research and development activities in new therapeutic areas."

Indiplon Update:

- Neurocrine has completed 14 Phase III efficacy and safety studies for New Drug Applications (NDA) submissions to the U.S. Food and Drug Administration (FDA). Results have confirmed that there are no safety issues that would preclude the filing of these NDAs. Pfizer and Neurocrine will continue to conduct additional studies to provide supplemental data on the efficacy and safety of *indiplon* to support and expand the label.
- Two long-term safety studies with *indiplon* (up to 12 months in duration) have been completed with the immediate release formulation, one in adults and one in the elderly with a total of 757 chronic insomnia patients in either open label studies or open label extensions of double-blind studies. Neurocrine has completed two long-term open label extension/safety studies of the modified release formulation, which enrolled 597 adult and elderly chronic insomnia patients. Preliminary safety results from these trials are consistent with our short-term trials and demonstrated that *indiplon* was safe and well tolerated throughout the treatment period.

GnRH for Women's Health Disorders and Prostate Cancer

In July 2004, Neurocrine completed two Phase I single and multiple dose clinical studies with the second generation GnRH candidate, NBI-56418 in approximately 50 healthy pre-menopausal women and in approximately 20 healthy males. Under single and multiple dosing, NBI-56418 demonstrated suppression of leutenizing hormone (LH) and estradiol in females while single doses of NBI-56418 in males resulted in suppression of LH and testosterone. In all studies, NBI-56418 was shown to be safe and well tolerated. The Company is moving ahead with advanced clinical trials with our other GnRH compounds to establish proof of concept in 2005:

- A back-up compound is scheduled to enter a Phase I trial in the fourth quarter of 2004.
- Initiation of Phase II studies with NBI-56418 are planned for endometriosis and uterine fibroids with results expected in the first half of 2005.

CRF for Stress Related Disorders

The Corticotropin Releasing Factor (CRF) program (CRF small molecule antagonist) partnered with GSK has identified multiple unique preclinical compounds that are in various stages of development for anxiety, depression and irritable bowel syndrome (IBS). A compound has been selected to begin Phase I clinical trials by year-end 2004. A back-up compound is also expected to enter Phase I clinical trials in the first half of 2005.

Altered Peptide Ligand (APL) for Multiple Sclerosis (MS)

Neurocrine initiated a Phase II clinical trial with NBI-5788 for the treatment of relapsing MS in July 2003 to evaluate the safety and tolerability of NBI-5788 (5 mg) in approximately 150 patients. The Phase II study is being conducted at 25 sites in the US and Canada and is expected to be completed by the first quarter of 2005. Results are expected at the end of 2005.

Altered Peptide Ligand for Type I Diabetes

Neurocrine has successfully completed four Phase I/II clinical trials with NBI-6024 for Type I Diabetes. Completed enrollment in a Phase II, dose-response, efficacy and safety trial in approximately 200 adults/adolescents with new onset Type 1 Diabetes. Preliminary results are expected in 2005.

Research Overview

Neurocrine's Research Department continues to advance novel small molecule compounds into clinical development. Neurocrine scientists are focusing on developing small molecule antagonists against G-protein coupled receptors (GPCRs). The Company expects to select one or more compounds for clinical development during 2004. Investigational New Drug Applications (INDs) are being filed from the following programs:

- A development compound from the MC-4 technology is expected to begin clinical studies in mid-2005. MC-4 represents a novel target for the treatment of obesity, cachexia and pain.
- Advanced lead compounds are also being evaluated from the MCH technology. MCH is believed to play an important role in the treatment of obesity, anxiety and depression. Neurocrine expects to file an IND in 2005.
- New orally active small molecule antagonists are being developed to treat various sleep disorders. Neurocrine expects to file an IND in early 2005.

Conference Call and Webcast Tomorrow Morning, July 29, 2004

Neurocrine will also host a live conference call and Webcast to discuss its second quarter financial results and provide a Company update tomorrow morning, Thursday July 29, 2004 at 11:00 AM Eastern Time (ET) / 8:00 AM Pacific Time (PT). Participants may access the live conference call by dialing 1-800-540-0559 (U.S.) or 785-832-1508 (International). The call can also be accessed via the Webcast through the Company's website at http://www.neurocrine.com or alternatively through a link provided by PRNewswire at http://www.neurocrine.com or alternatively one hour after the conclusion of the call by dialing 1-800-934-8425 (US) or 402-220-6995 (International) and will be archived until Thursday, August 12, 2004.

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, certain female and male disorders, anxiety, depression, diabetes, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, and autoimmunity. 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 CRF research programs will not lead to viable clinical candidates, that the GnRH receptor antagonist 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, the risk that additional clinical studies may be required to support filings for regulatory approval; risk that the Company may not complete indiplon Phase III clinical trials on the Company's projected timelines for various reasons, including the 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 report on Form 10-K for the year ended December 31, 2003 and most recent 10-Q filed for the first quarter ended, March 31, 2004. 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 Consolidated Statements of Operations (in thousands except for loss per share data)

Three Months Ended June 30. Six Months Ended June 30,

	2	2004		2003	2004		2003	
	(un:	audited)	(un	audited)	(un	audited)	(un	audited)
Revenues:								
Sponsored research and development	\$	2,506	\$	33,346	\$	7,875	\$	64,071
License fees and milestones		12,388		11,320		23,707		17,987
Grant income		155		302		408		626
Total revenues		15,049		44,968		31,990		82,684
Operating expenses:								
Research and development		22,969		52,323		49,357		100,647
General and administrative		5,469		5,135		10,752		9,879
Total operating expenses		28,438		57,458		60,109		110,526
Loss from operations		(13,389)		(12,490)		(28,119)		(27,842)
Other income and (expenses):								
Interest income and expense, net		2,259		2,211		4,612		4,276
Other income and expense, net		(1)		54		(4)		(49)
Total other income		2,258		2,265		4,608		4,227
Net loss	\$	(11,131)	\$	(10,225)	\$	(23,511)	\$	(23,615)
Net loss per common share:								
Basic and diluted	\$	(0.31)	\$	(0.33)	\$	(0.65)	\$	(0.76)
Shares used in the calculation of net loss per common share:	•	()	•	()	•	()		()
Basic and diluted		36,368		31,334		35,947		31,063

NEUROCRINE BIOSCIENCES, INC.

Condensed Consolidated Balance Sheets (in thousands)

	June 30, 2004	D	December 31, 2003	
	(unaudited)			
Cash, cash equivalents and marketable securities	\$ 326,53	7 \$	453,168	
Other current assets	9,51	7	18,641	
Total current assets	336,05	4	471,809	
Property and equipment, net	93,95	7	56,236	
Other non-current assets	116,46	8	26,910	
Total assets	\$ 546,47	9 \$	554,955	
Current liabilities	\$ 67,50	3 \$	110,012	
Long-term liabilities	67,43	5	53,823	
Stockholders' equity	411,54	1	391,120	
Total liabilities and stockholders' equity	\$ 546,47	9 \$	554,955	