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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): November 1, 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.)

12790 El Camino Real, San Diego, CA	**92130**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(858) 617-7600**

N/A

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

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ITEM 2.02 RESULTS OF OPERATION AND FINANCIAL CONDITION.

On November 1, 2004, Neurocrine Biosciences, Inc. announced its financial results for the quarter ended September 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.2. 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, ("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.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

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

Exhibit Number	Description of Exhibit
99.1	Press Release dated November 1, 2004

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 1, 2004

NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN
Paul W. Hawran
Executive Vice President
and Chief Financial Officer

Exhibit 99.1

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

NEUROCRINE BIOSCIENCES REPORTS THIRD QUARTER 2004 RESULTS

NEUROCRINE RECEIVES MILESTONES FOR SUCCESSFUL LONG TERM AND SLEEP MAINTENANCE RESULTS WITH INDIPLON

San Diego, CA, November 1, 2004 — Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended September 30, 2004. For the third quarter, the Company reported a net loss of $1.6 million, or $0.05 per share compared with a net loss of $9.8 million, or $0.31 per share, for the same period last year. For the nine months, the Company reported a net loss of $25.2 million, or $0.70 per share, as compared to $33.4 million, or $1.07 per share, for the same period last year.

Revenues for the third quarter of 2004 were $34.7 million compared with $29.3 million for the respective period last year. The increase in revenues for the third quarter is due to the recognition of milestones under the Pfizer Collaboration, offset by lower sponsored development revenue associated with the winding down of the *indiplon* program. During the third quarter of 2004, the Company achieved milestones totaling $17.5 million related to the successful results of Phase III clinical trials for long-term administration of *indiplon*, and positive results of Phase III clinical trials for sleep maintenance. License fees and milestones recognized were $26.0 million for the three months ended September 30, 2004 and $10.9 million for the three months ended September 30, 2003. The Company also recognized $7.3 million for the three months ended September 30, 2004 in the form of sponsored development funding compared to $16.1 million for the three months ended September 30, 2003.

Revenues for the nine months ended September 30, 2004 were $66.7 million compared with $111.9 million for the same period in 2003. The decrease in revenues for the nine month period is primarily due to lower sponsored development revenue associated with the winding down of the *indiplon* registration clinical program, offset by milestones achieved under research and development collaborations. The Company recognized $12.3 million, for the nine months ended September 30, 2004 in the form of sponsored development funding under the Pfizer collaboration agreement compared to $77.3 million, for the nine months ended September 30, 2003. License fees and milestones recognized under the Pfizer collaboration were $48.5 million for the nine months ended September 30, 2004 and $27.0 million for the nine months ended September 30, 2003.

Research and development expenses decreased to $32.3 million for the third quarter of 2004 compared with $37.5 million for the respective period in 2003. For the nine months ended September 30, 2004, research and development expenses were $81.7 million compared to $138.2 million for the same period last year. Decreased expenses primarily reflect the winding down of our *indiplon* program, offset by increased research and development expenses in other programs

and increased personnel and laboratory costs.

General and administrative expenses increased to $5.4 million for the third quarter of 2004 compared with $5.3 million during the same period last year. For the nine months ended September 30, 2004, general and administrative expenses were $16.2 million compared to $15.2 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 September 30, 2004 reflected total assets of $552.6 million, including cash, cash equivalents, marketable securities of $324.3 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 proud to report that Neurocrine has accomplished a significant corporate milestone with the submission of our Company's first New Drug Application (NDA) for *indiplon* immediate release and we expect to file a second NDA for *indiplon* modified release in November 2004. Our financial condition continues to be strong and we continue to manage at a controlled burn rate as we advance multiple new products through our broad pipeline," said Paul W. Hawran, Executive Vice President and Chief Financial Officer of Neurocrine Biosciences. "Based on the recent filing and anticipated filing of *indiplon* modified release, our guidance is for a loss of approximately $25 million for the year ending 2004. This guidance reflects achievement of the milestone relating to the FDA acceptance of the *indiplon* immediate release capsule NDA in 2004."

***Indiplon* Update:**
Neurocrine submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for regulatory approval of *indiplon* immediate release capsules for the treatment of insomnia October 18, 2004. The application contained safety and efficacy results from seven Phase III clinical trials with *indiplon* immediate release conducted in adult and elderly patients with transient and chronic insomnia. The NDA has been submitted in electronic common technical document format (e-CTD) and included data from a comprehensive safety and efficacy evaluation in approximately 3000 subjects. Neurocrine is developing two formulations of *indiplon*, an immediate release capsule and modified release tablet, for the treatment of multiple forms of insomnia. This first NDA submission contained non-clinical, clinical and manufacturing information that is common to both applications. Neurocrine expects to submit a second NDA for *indiplon* modified release tablets in November 2004.

***Indiplon* Peer Review Publications**
Neurocrine announced the publication of peer-reviewed studies of the first comprehensive description of the pharmacology of *indiplon*. Two papers have been published in the November 2004 issue of the Journal of Pharmacology and Experimental Therapeutics (JPET) on the mechanism of action of *indiplon*. In addition an abstract on the mechanism of action of *indiplon* was presented at the Society for Neuroscience 34th Annual Meeting in San Diego in late October. These non-clinical studies show that *indiplon* exerts its sedative/hypnotic effects by binding

selectively to the specific subtype of GABA-A receptors within the brain believed to be responsible for promoting sleep.

GnRH Antagonist for Women's Health Disorders
Neurocrine completed three Phase I single and multiple dose clinical studies with the second generation GnRH antagonist 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. As a lead in to long term studies, including those designed to demonstrate efficacy, the Company has completed enrollment in a six week study of NBI-56418 in healthy pre-menopausal women. Phase II studies with NBI-56418 in endometriosis and benign prostatic hyperplasia are planned for early 2005. Additionally a back-up compound will enter Phase I clinical trials in early November 2004.

Urocortin 2
In the third quarter 2004, Neurocrine initiated a Phase I clinical trial with its proprietary compound, urocortin 2, to evaluate the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of urocortin 2 in healthy volunteers and expects to initiate a Phase II clinical study in patients with mild to moderate congestive heart disease in early 2005. Based on our preclinical efficacy and safety data and its known role in human physiology, urocortin 2 is expected to have positive hemodynamic effects on cardiac output and blood pressure, which may benefit patients with congestive heart failure.

Urocortin 2 was discovered in the laboratory of Neurocrine's co-founder, Dr. Wylie W. Vale, Professor and Head, Clayton Foundation for Research for Peptide Biology from the Salk Institute. Neurocrine licensed urocortin 2 from the Clayton Foundation for Research to further expand the Company's franchise in corticotropin-releasing factor (CRF) research.

CRF for Stress Related Disorders
The Corticotropin Releasing Factor (CRF) program (CRF small molecule antagonist) partnered with GlaxoSmithKline (GSK) has identified multiple unique preclinical compounds that are in various stages of development for anxiety, depression and irritable bowel syndrome (IBS). The collaboration has selected a lead compound which is expected to begin Phase I clinical trials in November 2004. In addition, 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 ongoing at 28 sites in the US and Canada and will be expanded to four Eastern European countries before the end of 2004. Completion of the study is expected by the end of 2005. Results are expected in early-2006.

Altered Peptide Ligand for Type I Diabetes

Neurocrine has successfully completed four Phase I/II clinical trials with NBI-6024 for Type I Diabetes. Additionally the Company has completed enrollment in a Phase II, dose-response, efficacy and safety trial in approximately 200 adults/adolescents with new onset Type 1 Diabetes. Results from this trial are expected in 2006.

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 from the following programs:

- A development compound from the melanocortin-4 receptor (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 melanin concentrating hormone (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.

Neurocrine also presented 10 abstracts at the Society for Neuroscience 34th Annual Meeting in San Diego. Abstracts included data from the GnRH antagonist, CRF 1 antagonist and MCH antagonist programs.

Conference Call and Webcast Today at 5:00 PM Eastern Time
Neurocrine will also host a live conference call and webcast to discuss the third quarter results and provide a Company update today, Monday November 1, 2004 at 5:00PM Eastern Standard Time (EST), 2:00PM Pacific Standard Time (PST). Participants may access the live conference call by dialing 1-800-540-0559 (U.S.) or 785-832-1508 (International) providing the Conference ID#: NBIX. The call can also be accessed via the webcast through the Company's website at http://www.neurocrine.com or alternatively at PRNewswire: http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=68817&eventID=955161

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, 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, MC-4, MCH and sleep research programs will not lead to viable clinical candidates, that the GnRH receptor antagonist, urocortin 2 and altered peptide ligand clinical

candidates will not proceed to later stage clinical trials and risks and uncertainties associated with the Company's indiplon 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 regulatory authorities may reject our regulatory filings or find them incomplete or insufficient, risk that additional clinical studies may be required to support filings for regulatory approval; 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 additional planned indiplon regulatory filing, and specifically the indiplon modified release NDA, 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; risk that the indiplon labeling granted by regulatory authorities may limit the commercial success of indiplon; 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 report on Form 10-Q filed for the second quarter ended, June 30, 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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(unaudited)		(unaudited)	
Revenues:				
Sponsored research and development	$ 8,605	$ 17,580	$ 16,480	$ 81,651
License fees and milestones	26,096	11,319	49,803	29,306
Grant income	—	360	408	986
Total revenues	34,701	29,259	66,691	111,943
Operating expenses:				
Research and development	32,305	37,537	81,662	138,184
General and administrative	5,427	5,296	16,179	15,175
Total operating expenses	37,732	42,833	97,841	153,359
Loss from operations	(3,031)	(13,574)	(31,150)	(41,416)
Other income and (expenses):				
Interest income and expense, net	1,384	3,724	5,992	8,000
Other income and expense, net	—	16	—	(33)
Total other income	1,384	3,740	5,992	7,967
Net loss	$ (1,647)	$ (9,834)	$ (25,158)	$ (33,449)
Net loss per common share:				
Basic and diluted	$ (0.05)	$ (0.31)	$ (0.70)	$ (1.07)
Shares used in the calculation of net loss per common share:				
Basic and diluted	36,427	32,053	36,108	31,397

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

	September 30, 2004	December 31, 2003
	(unaudited)	
Cash, cash equivalents and marketable securities	$324,347	$453,168
Other current assets	12,311	18,641
Total current assets	336,658	471,809
Property and equipment, net	98,985	56,236
Other non-current assets	116,976	26,910
Total assets	$552,619	$554,955
Current liabilities	$ 72,112	$110,012
Long-term liabilities	67,943	53,823
Stockholders' equity	412,564	391,120
Total liabilities and stockholders' equity	$552,619	$554,955