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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): December 21, 2004

**NEUROCRINE BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other  
jurisdiction of  
incorporation or  
organization)

**0-28150**  
(Commission File  
Number)

**33-0525145**  
(IRS Employer Identification No.)

**12790 El Camino Real**  
(Address of principal executive offices)

**92130**  
(Zip Code)

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

**N/A**

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4 (c))
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**ITEM 8.01 OTHER EVENTS.**

On December 21, 2004 Neurocrine Biosciences, Inc. announced that the U.S. Food and Drug Administration has not accepted the Company's New Drug Application (NDA) for *indiplon* immediate release due to difficulties encountered in navigating the electronic NDA. The formatting issues are based solely on technical difficulties with the electronic navigation and do not pertain to the content of the filings. The full text of the press release issued with this announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K.

**ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.**

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

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
99.1	Press Release dated December 21, 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: December 21, 2004

NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN

Paul W. Hawran

Executive Vice President and Chief Financial Officer

## FOR IMMEDIATE RELEASE

Investor Contacts:  
Elizabeth Foster or Claudia Jones  
Neurocrine Biosciences  
(858) 617-7600

INDIPLON IR NDA (NEW DRUG APPLICATION) TO BE REFORMATTED  
DUE TO DIFFICULTIES IN ACCESSING PORTIONS OF THE  
ELECTRONIC NDA

San Diego, CA, December 21, 2004 - Neurocrine Biosciences, Inc. (NASDAQ:NBIX) announced today that the U.S. Food and Drug Administration (FDA) has not accepted the Company's NDA for indiplon immediate release (IR) due to difficulties encountered in navigating the electronic NDA. Neurocrine is working to resolve the issues relating to the navigation of the electronic filing and to minimize any impact on the expected timelines for approval and launch of indiplon. The indiplon modified release (MR) filing is currently under review with the FDA and the Company is also working to address any potential formatting issues with the MR filing. The formatting issues are based solely on technical difficulties with the electronic navigation and do not pertain to the content of the filings.

The IR NDA was submitted on October 19, 2004 to the Anesthesia and Critical Care Division of the FDA and was transferred for review to the Neuropharm Division of the FDA on November 19, 2004. The Neuropharm Division is now responsible for the indiplon review and approval process. The filing contains studies which comprise one of the most extensive programs conducted to date in insomnia, with data from 68 clinical trials and over 80 preclinical studies. The NDA was filed in eCTD electronic format, which contains over 1,350 volumes or 475,000 pages of data.

Conference Call and Web Cast Today: December 21, 2004

Neurocrine will host a live conference call and web cast today, December 21, 2004 at 9:00 AM Eastern Standard Time (6:00 AM Pacific Standard Time). Participants may access the live conference call by dialing 1-800-540-0559 (U.S.) or 785-832-2422 (International) and using the identification code: NBIX. The call can also be accessed via the web cast through the Company's website at <http://www.neurocrine.com>. A replay of the conference call will be available approximately one hour after the conclusion of the call by dialing 1-877-856-8966 (US) or 402-220-1610. The call will be archived until January 4, 2005.

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, but not limited to, risk 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; risk that the Company will not be able to reformat the indiplon IR NDA within the Company's projected timelines; risk that the Company will be unable to reformat the indiplon IR NDA in a manner acceptable to the FDA; risk that the FDA may require that the indiplon MR NDA also be reformatted; 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 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 third quarter ended, September 30, 2004. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.