

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 22, 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 November 22, 2004 Neurocrine Biosciences, Inc. announced its submission of a new drug application to the U.S. Food and Drug Administration for indiplon modified release tablets. 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:

Exhibit Number	Description of Exhibit
99.1	Press Release dated November 22, 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 22, 2004

NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN

Paul W. Hawran

Executive Vice President and Chief Financial Officer

For Immediate Release

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**NEUROCRINE SUBMITS NEW DRUG APPLICATION (NDA) FOR INDIPLON
MODIFIED RELEASE TABLETS FOR THE TREATMENT OF INSOMNIA**

San Diego, CA, November 22, 2004 — Neurocrine Biosciences, Inc. (NASDAQ:NBIX) announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for regulatory approval of *indiplon* modified release tablets for the treatment of insomnia. The application contains safety and efficacy results from 8 Phase III clinical trials with *indiplon* modified release conducted in adult and elderly patients with transient and chronic insomnia. The NDA for *indiplon* immediate release capsules was submitted to the FDA on October 18 of this year.

This NDA submission contains manufacturing and clinical information specific to the modified release formulation. The first NDA submitted in October for *indiplon* immediate release included non-clinical, clinical, and manufacturing information that was common to both applications. The NDAs have been submitted in electronic common technical document format (e-CTD) and include data from a comprehensive safety and efficacy evaluation in over 7500 subjects.

“Patients with insomnia experience a wide range of symptoms such as trouble falling asleep, trouble staying asleep, and waking up frequently during the night. However, no two patients are alike as symptoms vary from patient to patient. The two formulations of *indiplon* will be an important advance in allowing physicians to tailor treatment to help improve patients’ individual insomnia symptoms and, as a result, sleep quality. Clinical trials consistently showed that patients fell sleep quickly and stayed asleep longer when modified release tablets were taken at bedtime,” said Dr. Thomas Roth, Director Sleep Disorders Center, Henry Ford Hospital.

“The submission of the two NDAs for *indiplon* represents a great achievement for Neurocrine that will turn the focus of the Company towards commercialization. We believe that *indiplon* will set a new standard in the way physicians treat and manage insomnia. We are now moving forward with our partner, Pfizer, in preparing for the commercialization of *indiplon*, while building and training the Neurocrine sales force to co-detail Zolofit® with Pfizer to psychiatrists,” said Gary A. Lyons, President and CEO of Neurocrine Biosciences.

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About Indiplon

Indiplon is a unique non-benzodiazapine agent that acts on a specific site of the GABA-A receptor. *Indiplon* has been shown to bind selectively to the specific subtype of GABA-A receptors within the brain believed to be responsible for promoting sleep. Two formulations of *indiplon*, immediate release capsules and modified release tablets, have been evaluated in clinical trials to address different types of sleep problems. *Indiplon* was licensed from DOV Pharmaceutical in 1998.

Insomnia is a prevalent condition in the United States, with approximately 40 percent of the adult population reporting trouble sleeping a few nights per week or more, according to the National Sleep Foundation's (NSF) Sleep in America Poll 2002. Approximately 35 percent of the adult population reports that they have experienced insomnia every night or almost every night within the past year. Insomnia remains a disorder with high unmet medical needs, including problems of frequent night time awakenings and difficulty falling back to sleep, sometimes referred to as sleep fragmentation.

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, 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.

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