

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): October 19, 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.)

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ITEM 8.01 OTHER EVENTS.

On October 19, 2004 Neurocrine Biosciences, Inc. announced its submission of a new drug application to the U.S. Food and Drug Administration for indiplon immediate release capsules. 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 October 19, 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: October 19, 2004

NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN

Paul W. Hawran

Executive Vice President and Chief Financial Officer

Investor Contacts:

Elizabeth Foster or Claudia Jones of Neurocrine Biosciences
(858) 617-7757 or (858) 617-7759

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(212) 798-9734

NEUROCRINE SUBMITS NEW DRUG APPLICATION (NDA) FOR INDIPLON
IMMEDIATE RELEASE CAPSULES FOR THE TREATMENT OF INSOMNIA

San Diego, CA, October 19, 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 immediate release capsules for the treatment of insomnia. The application contains 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. Neurocrine is developing two formulations of indiplon, an immediate release capsule and modified release tablet, for the treatment of multiple forms of insomnia. Neurocrine expects to submit a second NDA for indiplon modified release tablets in November. This first NDA submission contains non-clinical, clinical and manufacturing information that is common to both applications.

The NDA has been submitted in electronic common technical document format (e-CTD). It includes data from a comprehensive safety and efficacy evaluation in approximately 3000 subjects.

"Insomnia affects over 85 million younger and older adults every year and is becoming more recognized by physicians as a disease that affects many aspects of patients' health and well-being. Insomnia is not a one size fits all condition as patients experience various types of sleep difficulties and symptoms such as trouble falling asleep, trouble staying asleep or waking up frequently during the night. Indiplon capsules and tablets have consistently demonstrated robust efficacy and safety in repeated clinical evaluations, measuring multiple parameters of sleep difficulties. These results confirm that indiplon will offer physicians a significant improvement in the diagnosis and treatment of patients' individual sleep needs," said Dr. Thomas Roth, Director Sleep Disorders Center, Henry Ford Hospital.

"The submission of the indiplon NDA is a significant milestone for Neurocrine, the first in the Company's history. Indiplon is an important advancement in the treatment of insomnia as it was specifically designed and developed to address the individual sleep needs of patients. Indiplon capsules have consistently demonstrated that patients fall asleep faster, have improved sleep quality and sleep duration. Phase III safety and efficacy clinical trials have shown that indiplon capsules can be taken during the night for patients who suffer from nighttime awakenings and have been shown to be safe and effective for long term chronic usage. We are pleased to have Pfizer, the leading global pharmaceutical company, as our partner in the development and commercialization of indiplon," 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, are being 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 prolonged awakenings during the night with difficulty falling back to sleep.

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 successfully co-ordinate the completion and submission of additional planned indiplon regulatory filings, 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 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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