



**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): June 15, 2006

**NEUROCRINE BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

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

**0-22705**  
(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))
- 
-

## **TABLE OF CONTENTS**

[Item 8.01 Other Events](#)

[Item 9.01 Financial Statements and Exhibits](#)

[SIGNATURES](#)

[EXHIBIT 99.1](#)

---

## [Table of Contents](#)

### **Item 8.01 Other Events**

On June 15, 2006, Neurocrinc Biosciences, Inc. issued a press release to provide an update on the Company's review of the indiplon action letters and announce that the Company has requested a meeting with the Food and Drug Administration (FDA).

### **Item 9.01 Financial Statements and Exhibits**

99.1 Press Release dated June 15, 2006

---

**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: June 16, 2006

NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN

Paul W. Hawran

Executive Vice President and Chief

Financial Officer

**FOR IMMEDIATE RELEASE**

Neurocrine Contacts:

Elizabeth Foster or Claudia Woodworth

(858) 617-7600

**NEUROCRINE COMPLETES REVIEW OF INDIPLON ACTION LETTERS**

San Diego, CA, June 15, 2006- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) announced that the Company has completed its review of the indiplon action letters and has requested a meeting with the Food and Drug Administration (FDA). During the past several weeks the Company has been preparing a briefing document which will be submitted to the FDA. This briefing document will assist the Company in articulating its understanding of the issues communicated by the FDA in the May 15th action letters. The action letters included an Approvable Letter for 5 mg and 10 mg immediate release indiplon capsules and a Not Approvable Letter for indiplon 15 mg extended release tablets received by the Company on May 15, 2006. The feedback from this FDA meeting will help the Company determine plans in moving forward.

The FDA Approvable Letter for indiplon 5 mg and 10 mg capsules requested that the Company reanalyze data from certain preclinical and clinical studies to support approval of indiplon capsules for sleep initiation and middle of the night dosing. The FDA also requested reexamination of the safety analysis for the elderly population. The FDA may require additional clinical and/ or pre-clinical safety data.

The FDA Not Approvable Letter for indiplon 15 mg tablets requested that the Company reanalyze certain safety and efficacy data. The letter also questioned the sufficiency of the Company's objective sleep maintenance clinical data with the 15 mg tablet in view of the fact that the majority of the Company's indiplon tablet studies were conducted with doses higher than 15 mg. Additional clinical data will likely be required.

The Company believes that information it included in the submissions and subsequent amendments submitted during the review period have provided responses to a number of the issues raised by the FDA in the action letters. These amendments include reanalysis of certain data for indiplon capsules and a polysomnographic clinical study with indiplon 15 mg tablets.

"On May 17, we notified the FDA that we intend to further amend both applications to respond to the deficiencies raised by the FDA. Our immediate focus is to meet with the FDA to determine the nature and scope of any additional preclinical and/or clinical work the agency may require for approval," said Gary Lyons, President and Chief Executive Officer. "We will make final plans for the NDA resubmissions once we have clarified this in conference with the FDA. We are also expecting to amend financial guidance in our second quarter financial webcast."

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, 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 relating to Neurocrine's indiplon program that could cause actual results to differ materially from those indicated in the forward-looking statements. 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 address issues and or requests set forth in the action letters from the FDA in a timely manner; risk that the Company will not be able to address issues and or requests set forth in the action letters from the FDA in a manner acceptable to the FDA; the risk that FDA may reject any future indiplon regulatory filings or find them incomplete or insufficient; risk that indiplon approval and subsequent commercialization may be significantly delayed; and the other risks described in Neurocrine's annual report on Form 10-K for the year ended December 31, 2005 and quarterly report on Form 10-Q for the quarter ended March 30, 2006. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.*

###