# UNITED STATES 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): January 22, 2007

## 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)
- o 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))

### ITEM 8.01 OTHER EVENTS.

On January 22, 2007, the Company announced that it plans to resubmit its New Drug Application (NDA) for indiplon capsules by the end of 2nd Quarter 2007.

#### ITEM 9.01. FINANCIAL STATEMENTS and EXHIBITS

99.1 Press release dated January 22, 2007.

### **SIGNATURES**

Officer

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: January 23, 2007

NEUROCRINE BIOSCIENCES, INC.

/s/ Timothy P. Coughlin Timothy P. Coughlin Vice President and Chief Financial

### EXHIBIT INDEX

Exhibit Number 99.1

Document Description
Press release dated January 22, 2007

#### FOR IMMEDIATE RELEASE

#### **Investor Contacts:**

Elizabeth Foster (858) 617-7600

# NEUROCRINE ANNOUNCES PLANS TO RESUBMIT NDA FOR INDIPLON CAPSULES IN Q2 2007

San Diego, CA, January 22, 2007 — Neurocrine Biosciences, Inc. (NASDAQ:NBIX) announced today that the Company plans to resubmit its New Drug Application (NDA) for *indiplon* capsules by the end of 2<sup>nd</sup> Quarter 2007. The decision to accelerate the resubmission is based on the results of interactions with the Food and Drug Administration (FDA) regarding further analyses of data previously submitted on *indiplon* capsules, as well as reviewing this data with independent statistical, regulatory and clinical consultants. Neurocrine expects that the FDA will characterize the resubmission as Class 2 which has a targeted review timeline of 6 months.

"We believe that *indiplon* will offer an important new alternative for the treatment of insomnia by providing flexibility to treat insomnia as needed, to help patients quickly fall asleep or return to sleep after a nighttime awakening," said Gary Lyons, President & CEO of Neurocrine Biosciences.

The Company's discussions with the FDA on the *indiplon* capsules NDA have been focused on the actions necessary to provide a complete response to the agency's questions thus allowing for its resubmission. The FDA requested that the resubmission include further analyses and modifications of analyses previously submitted to address questions raised by the Agency in its initial review. The FDA also requested, and the Company has completed, a supplemental pharmacokinetic/food effect profile of *indiplon* capsules including several meal types. No other trials were requested for the re-submission. The Company has decided that it will not conduct an additional 3-month safety and efficacy study as previously announced but rather direct these resources to pre-commercialization and Phase IIIb/IV activities as well as to continue to evaluate *indiplon* for traditional sleep maintenance.

Neurocrine Biosciences, Inc. is a product-based biopharmaceutical company focused on neurological and endocrine diseases and disorders. The product candidates address some of the largest pharmaceutical markets in the world including insomnia, anxiety, depression, endometriosis, irritable bowel syndrome, pain, and autoimmunity. Neurocrine Biosciences, Inc. news releases are available through the Company's website via the Internet at <a href="http://www.neurocrine.com">http://www.neurocrine.com</a>

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 in general as well as, risk and uncertainties associated with the Company's indiplon program and planned commercialization

activities, including but not limited to; risk that we will be unable to resubmit the indiplon capsule NDA in a timely manner or at all; risk that regulatory authorities may refuse to file our resubmission of the indiplon capsule NDA; risk that regulatory authorities may find our resubmission of the indiplon capsule NDA incomplete or insufficient or otherwise unapprovable or that approval may be delayed; risk that following approval of indiplon capsules, commercialization may be delayed for any of a number of reasons including market conditions and product supply; risk that we will not be able to independently commercialize indiplon capsules or find a marketing partner on reasonable terms or at all; risk that the indiplon capsule labeling granted by regulatory authorities may limit the commercial success of indiplon capsules; and risk relating to market acceptance of indiplon capsules following marketing approval; in addition to the other risks described in the Company's report on Form 10-K for the year ended December 31, 2005 and Form 10-Q for the quarter ended September 30, 2006. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.