

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 earliest event reported): November 16, 2001

Neurocrine Biosciences, Inc.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or Other  
Jurisdiction of Incorporation)

0-28150  
(Commission File Number)

33-0525145  
(I.R.S. Employer  
Identification No.)

10555 Science Center Drive, San Diego, California  
(Address of Principal Executive Offices)

92121  
(Zip Code)

Registrant's telephone number, including area code: (858) 658-7600

This Current Report on Form 8-K is filed by Neurocrine Biosciences, Inc., a Delaware corporation (the "Company"), in connection with the matters described herein.

Item 5. Other Events.

On November 16, 2001, the Company announced that it has initiated the first pivotal Phase III clinical trial of NBI-34060 in approximately 500 patients with chronic (primary) insomnia. A copy of the Company's press release announcing the initiation of the clinical trial, dated November 16, 2001, is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 7. Exhibits.

(c)	Exhibits.	
	Exhibit	Description of Exhibit
	Number	-----
	99.1	Press Release, dated November 16, 2001.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 16, 2001

NEUROCRINE BIOSCIENCES, Inc.

By: /s/ PAUL W. HAWRAN

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Paul W. Hawran  
Senior Vice President and  
Chief Financial Officer

FOR IMMEDIATE RELEASE  
Contact at Neurocrine Biosciences  
Elizabeth Foster or Paul Hawran  
(858) 658-7600

Neurocrine Biosciences Initiates Phase III Clinical Trial for  
NBI-34060 In Chronic (Primary) Insomnia

San Diego, CA, November 16, 2001-Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced that it has initiated the first pivotal Phase III clinical trial of NBI-34060 in approximately 500 patients with chronic (primary) insomnia. The Phase III clinical trial is a randomized, double blind, parallel-group, multi-center study to evaluate the safety of two doses of NBI-34060 Immediate Release (IR) for the long-term treatment of chronic (primary) insomnia in adults. The trial will be conducted in approximately 40 medical sites in the United States and Europe.

"This trial is a major turning point for Neurocrine as we begin our first Phase III program in the history of the Company," said Gary A. Lyons, President and CEO of Neurocrine Biosciences.

"Two additional pivotal Phase III trials with NBI-34060-IR are planned to initiate shortly. We are implementing an aggressive Phase III clinical evaluation of NBI-34060 to support registration of this new sedative hypnotic for short-term and long-term treatment of insomnia," said Henry Pan, M.D. Ph.D, Executive Vice President of Clinical Development and Chief Medical Officer for Neurocrine Biosciences.

Background on NBI-34060 for Insomnia  
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NBI-34060 is a non-benzodiazepine that acts on a specific site of the GABA-A receptor. It is through this same mechanism that the non-benzodiazepine therapeutics currently on the market produce their sleep-promoting effects.

Insomnia is a prevalent neurological disorder in the United States, with about one-half of the adult population reporting trouble sleeping a few nights per week or more, according to the National Sleep Foundation (NSF). Approximately 29% of the adult population reports that they experience insomnia every night or almost every night. Despite this widespread prevalence, insomnia remains a disorder with high unmet medical needs, including the ability to maintain sleep throughout the night without next-day residual effects.

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, malignant brain tumors and peripheral cancers, diabetes, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, stroke, and certain female health disorders. 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 contains 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 development programs and business and finances including, but not limited to, risk that Neurocrine's development programs will not successfully proceed through all phases of clinical trials or that in later stage clinical trials will not show that Neurocrine's product candidates are effective in treating humans; determinations by regulatory and governmental authorities; uncertainties relating to patent protection and intellectual property rights of third parties; impact of competitive products and technological changes; availability of capital and cost of capital; and other material risks. A more complete description of these risks can be found in the Company's Annual Form 10K for the year ended December 31, 2000, as amended, the quarterly report on form 10Q for the quarter ended September 30, each of which should be read before making any investment in Neurocrine common stock. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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