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# 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): April 5, 2000

NEUROCRINE BIOSCIENCES, INC. (Exact name of registrant as specified in its charter)

CALIFORNIA
(State or other
jurisdiction of
incorporation)

0-28150 (Commission File Number) 33-0525145 (IRS Employer Identification Number)

10555 Science Center Drive, San Diego, CA (Address of principal executive offices)

92121 (Zip Code)

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

N/A

(Former name or former address, if changed since last report.)

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#### ITEM 5. OTHER EVENTS

On April 5, 2000, Neurocrine Biosciences, Inc. announced that Janssen Pharmaceutica, N.V. intends to substitute its lead CRF antagonist (R121919) with a Neurocrine/Janssen back-up compound resulting from the expanded research collaboration entered into during 1999. The decision to discontinue further development of R121919 was based on observations of reversible increases in liver enzymes in two volunteers participating in an expanded safety trial conducted in the United Kingdom. Approximately 250 subjects to date have been treated in various clinical trials with no other observed safety issues.

A copy of the press release issued by the Registrant on April 5, 2000 concerning the foregoing transactions are filed herewith as Exhibits 99.1 and is incorporated herein by reference.

### ITEM 7. FINANCIAL STATEMENTS, PRO-FORMA FINANCIAL INFORMATION AND EXHIBITS

- (a) FINANCIAL STATEMENTS OF BUSINESS ACQUIRED. Not applicable.
- (b) PRO-FORMA FINANCIAL INFORMATION. Not applicable.
- (c) EXHIBITS. The following exhibits are filed herewith:
  - 99.1 Press Release of Registrant, dated April 5, 2000, announcing Janssen Pharmaceutica's replacement of R121919 with a back-up compound

#### 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: 04/05/00 By:/s/ Paul W. Hawran

Paul W. Hawran

Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

### EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release of Registrant, dated April 5, 2000, announcing Janssen Pharmaceutica's replacement of R121919 with a back-up compound

FOR IMMEDIATE RELEASE: Contact at Neurocrine Biosciences: Claudia Jones or Paul Hawran (858) 658-7600

## NEUROCRINE ANNOUNCES THAT JANSSEN PHARMACEUTICA INTENDS TO REPLACE R121919 WITH A BACK-UP COMPOUND

NEUROCRINE CRF PROGRAM ON TRACK FOR PHASE I TRIALS TO BEGIN 2ND HALF 2000 WITH UNPARTNERED CRF ANTAGONIST COMPOUND FOR ANXIETY/DEPRESSION

San Diego, CA, April 5, 2000 - Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today that Janssen Pharmaceutica intends to substitute its lead CRF antagonist (R121919) with a Neurocrine/Janssen back-up compound resulting from the expanded research collaboration entered in 1999. The decision to discontinue further development of R121919 was based on observations of reversible increases in liver enzymes in two volunteers participating in an expanded safety trial conducted in the United Kingdom. Approximately 250 subjects to date have been treated in various clinical trials with no other observed safety issues. Separately, Neurocrine also confirmed that Phase I clinical trials are scheduled to begin in the 2nd half of 2000 for its unpartnered CRF antagonist compound for anxiety/depression.

"Janssen remains committed to the CRF technology. This technology continues to be important to us," said Rolondo Gutierrez, M.D., Global Product Leader Antidepressants and Anxiolytics of Janssen Pharmaceutica. "We have learned a great deal about the CRF mechanism from our preclinical and clinical experience with this compound. We believe this knowledge will help us to accelerate the clinical development of future potential CRF antagonist compounds."

"Recently, considerable evidence from preclinical and clinical investigations have provided even more support for the CRF hypothesis of depression," said Charles Nemeroff, M.D., Ph.D., Chairman and Professor of the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine. "One piece of this expanding database is the promising results with the CRF1 receptor antagonist, R121919. This safety issue which appears unrelated to the CRF receptor mechanism unfortunately precludes further clinical development of this compound. I have little doubt that this novel class of antidepressants/anxiolytics will represent a breakthrough in the treatment of these devastating disorders."

Neurocrine also confirmed today that the clinical development of its unpartnered CRF antagonist compound for anxiety/depression is scheduled to begin human clinical trials in the 2nd half 2000. This proprietary compound is from a novel chemical series which is distinct from R121919. Based on preclinical studies the Neurocrine proprietary compound has demonstrated improved specificity and greater potency together with excellent pharmacokinetic properties.

"The results of an unrelated open label Phase IIa study conducted at the Max Planck Institute have provided encouraging results regarding the validity of the CRF mechanism as a potential therapeutic target for anxiety and depression," said Florian Holsboer, M.D., Ph.D., and Director at the Max Planck Institute fur Psychiatrie in Munich, Germany. "There is no indication of a causal relationship between the pharmacology of the compound and the safety concerns that have arisen by the two volunteers in the expanded safety study in the United Kingdom."

"While we are disappointed by these developments, the Janssen work has generated valuable knowledge with respect to the CRF mechanism which will guide our future development," said Gary Lyons, President & CEO. "In addition to our unpartnered CRF program, our expanded collaboration with Janssen has produced multiple back-up compounds from which the next series of clinical candidates will be selected. We look forward to continuing and perhaps expanding our collaboration with Janssen in this field."

CRF was first identified and cloned by Neurocrine co-founder, Dr. Wylie Vale and his colleagues at the Salk Institute. Neurocrine holds the patent rights to the CRF family of receptors and has developed multiple series of selective, potent, small molecule antagonists for these receptors. CRF functions as a neurotransmitter in the brain and plays a critical role in coordinating the body's responses to stress. The CRF1 receptor subtype largely mediates these effects. In preclinical models, selective CRF1 receptor antagonists block stress responses providing evidence that this novel mechanism may result in improved anti-anxiety and anti-depressant drugs. CRF1 antagonists have not shown evidence of sexual dysfunction or addictive properties in preclinical models. In

addition, some data suggest that CRF1 antagonists may have a more rapid onset of action compared to the currently marketed anti-depressants.

Including R121919, Neurocrine has now advanced five programs into clinical trials. Neurocrine is conducting several Phase II trials with NBI-34060 for insomnia, a Phase I/II with NBI 3001 for glioblastoma and a Phase I with NBI 6024 with Altered Peptide Ligand for Type I diabetes. In addition, as the company has recently announced, Neurocrine is planning a Phase II clinical trial of its APL compound for multiple sclerosis following positive results from an earlier Phase II trial.

Neurocrine Biosciences is a leading neuroscience company focused on the discovery and development of novel therapeutics for neuropsychiatric, neuroinflammatory and neurodegenerative diseases and disorders. The Company's neuroscience, endocrine and immunology disciplines provide a unique biological understanding of the molecular interaction between central nervous, immune and endocrine systems for the development of therapeutic interventions for anxiety, depression, insomnia, stroke, malignant brain tumors, multiple sclerosis, obesity and diabetes.

Neurocrine Biosciences, Inc. news releases are available through the Company's website via the Internet at http://www.neurocrine.com.

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historical facts, this press release may contain In addition to 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 CRF antagonist development programs including, but not limited to, risks and uncertainties associated with, or arising out of, clinical development of products including risk that development candidates, will not successfully proceed through early clinical trials or that in later stage clinical trials will not show that they 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 Form 10K for December 31, 1999. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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