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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): March 8, 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))
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### **Item 8.01 Other Events**

On March 8, 2006, Neurocrine Biosciences, Inc. issued a press release to provide an update on the Company's drug development pipeline, including the discontinuing of the development of the APL-MS program. The full text of the press release issued in connection with the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

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

99.1 Press Release dated March 8, 2006

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**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: March 13, 2006

NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN

Paul W. Hawran

Executive Vice President and Chief

Financial Officer

**FOR IMMEDIATE RELEASE**

Contact at Neurocrine Biosciences  
Elizabeth Foster or Claudia Woodworth  
(858) 617-7600

**NEUROCRINE BIOSCIENCES ANNOUNCES RESULTS OF THE PHASE II STUDY IN MULTIPLE SCLEROSIS****THE COMPANY ALSO PROVIDES UPDATE ON INDIPLON AND THE 2006 DEVELOPMENT PIPELINE**

San Diego, CA, March 8, 2006 — Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced that the results of its Phase II clinical trial using its altered peptide ligand (APL) technology for Multiple Sclerosis (MS) did not meet its primary endpoint and demonstrate efficacy although the product was safe and well tolerated. Based on these results, the Company has discontinued the development of its APL-MS program. The Company will complete its other APL Phase II study, which is evaluating the APL technology for the treatment of Type-1 diabetes, utilizing a different APL epitope. Results of this trial are expected in the 3<sup>rd</sup> Quarter of 2006.

In other developments, the Company continues to anticipate that the proposed rule in the Federal Register for the DEA to place indiplon into Schedule IV of the Controlled Substances Act (CSA) is expected to occur shortly. This proposed action will be based on a recommendation from the Acting Assistant Secretary for Health of the Department of Health and Human Services (DHHS) and on an evaluation of the relevant data by DEA. Based on discussions with the DEA, the Company expects the DEA will complete its process in parallel with the FDA review.

In addition, the Company reported on the progress of the other Clinical Development Goals for 2006. Neurocrine is focusing on the advancement of several programs from early to mid-stage clinical development for multiple therapeutic indications. The Company's main clinical development candidates include an oral, small-molecule GnRH antagonist for the treatment of endometriosis and benign prostate hyperplasia, urocortin 2 for congestive heart failure (CHF), and a CRF antagonist for anxiety/depression and irritable bowel syndrome (IBS). The Company is also advancing a back-up compound for GnRH and has brought forward into clinical development a back-up CRF antagonist. In addition, the Company has initiated a Phase I clinical trial for a new compound, an H1 antagonist, NBI-75043, for the treatment of insomnia.

"Our Phase II study in multiple sclerosis patients showed APL-MS to have an excellent safety profile, but unfortunately the study did not achieve statistical significance in efficacy in the 157 patients tested over the 9-month treatment period. Antigen specific recruitment of TH2 cells to treat autoimmune disorders is a very appealing concept. We will continue to evaluate the clinical benefits of the APL epitope to treat Type-1 diabetes, and will review this program based on Phase II results expected mid-year. Neurocrine is continuing to focus its resources on several new product candidates, which are currently advancing

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through development, and we will report on these Phase II and proof of concept results throughout this year,” said Wendell Wierenga, Ph.D, Executive Vice President of Research and Development for Neurocrine Biosciences.

#### **GnRH for Endometriosis Is On Track To Report Results in April 2006**

Enrollment has been completed in the first three-month period of an ongoing Phase II study with NBI-56418 in 76 patients with endometriosis. The primary endpoint of the study is reduction in endometriotic pain as measured with the Composite Pelvic Sign and Symptoms Score (CPSSS), a validated clinical endpoint. Results from the 12-week, double-blind, placebo-controlled segment of the study are expected to be announced in early 2<sup>nd</sup> Quarter; the three-month safety follow-up period continues into the 2<sup>nd</sup> Quarter of 2006. A second Phase II study in patients with endometriosis was initiated in December 2005 to more fully explore dose response. This study, a multi-dose, double-blind placebo-controlled trial is enrolling 72 patients and is also designed to assess safety and efficacy over a three-month period with the primary endpoint of reduction in endometriotic pain as measured by CPSSS. Preliminary results are expected to be announced in the 3<sup>rd</sup> Quarter of 2006. In addition, the Company is preparing a third Phase II study, which will examine endometriosis in a six-month trial, which will measure efficacy and impact of treatment on bone mineral density. Finally the company recently started a Phase I study in male volunteers as part of the Benign Prostate Hyperplasia development program and expects to enter into Phase II studies late in 2006.

#### **Preliminary Positive Results With Urocortin 2 for Congestive Heart Failure**

In November 2005, Neurocrine filed an IND application with the FDA to initiate a US Phase II study in stable CHF patients to further evaluate dose/response of urocortin 2 when administered over 4 hours. Initial results indicate that urocortin 2 is generally well tolerated and that the predicted hemodynamic effects on systolic and diastolic blood pressure, heart rate, cardiac work and, most importantly, cardiac output occur over the entire 4-hour infusion. Full study results are anticipated in the 3<sup>rd</sup> Quarter of 2006. This extended-infusion data will then provide guidance for dosing in the planned Phase IIb studies in the target population of patients with acute decompensated heart failure (ADHF). Results of this ADHF study are anticipated in the second half of 2007.

#### **Corticotropin Releasing Factor (CRF) Antagonist Anticipated To Advance To Phase II Clinical Trials In 2006**

In collaboration with GlaxoSmithKline (GSK), the CRF program is progressing as planned through early stage clinical trials. Phase I trials are ongoing and GSK is planning to initiate Phase II trials in Anxiety/Depression during 2006.

In addition to the Anxiety and Depression indication, GSK has an ongoing development program for CRF<sub>1</sub> receptor antagonists in Irritable Bowel Syndrome (IBS). GSK intends to advance the lead CRF<sub>1</sub> receptor antagonist compound into Phase II studies in irritable bowel syndrome during 2006.

Irritable bowel syndrome is a gastrointestinal disease that affects approximately 30 million people in the United States, accounting for over \$25 billion in direct and indirect costs

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each year, according to the International Foundation for Functional Gastrointestinal Disorders. Although the exact pathophysiology of IBS is not well understood, there is increasing evidence to suggest that underlying inflammation may influence the symptoms of pain and changes in bowel pattern experienced by patients. Irritable bowel syndrome can be a lifelong, intermittent disease, involving chronic or recurrent abdominal pain and frequent diarrhea or constipation.

#### **Altered Peptide Ligand (APL) for Type 1 Diabetes**

Neurocrine has completed enrollment in a Phase II, dose-response, safety, tolerability and efficacy trial in approximately 188 adults/adolescents with new onset Type-1 diabetes. Results from this study are expected in the 3<sup>rd</sup> Quarter of 2006.

#### **Additional Compound for Insomnia Enters Clinical Development**

Neurocrine initiated a Phase I study in the 1<sup>st</sup> Quarter of 2006 of a new compound, NBI-75043, for the treatment of insomnia. NBI-75043 is an orally-active, highly-selective and short-acting agent. The Phase I studies which will evaluate the safety and PK of single and multiple doses as well as selected sleep-related parameters will be completed in the second half of 2006, at which time the company anticipates to initiate early Phase II proof of concept studies.

#### **Additional Research Programs**

Neurocrine's Research Group continues to advance novel small molecule compounds into clinical development. Neurocrine scientists are focusing on developing small molecule antagonists against G-protein coupled receptors. In addition, Neurocrine scientists are also currently reviewing in preclinical studies A2A antagonists for the treatment of Parkinson's disease.

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, 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 and research programs in general including, but not limited to, risk and uncertainties associated with the Company's indiplon program and research and development activities. Specifically, the risks and uncertainties the Company faces with respect to its indiplon program include, but are not limited to risk that regulatory authorities may find either or both of our indiplon NDAs incomplete or insufficient or for any other reason not approvable; risk associated with our reliance on our strategic alliance partner for manufacturing and commercialization of indiplon; risk that following approval of indiplon commercialization may be delayed for any of a number of reasons including market conditions and product supply; risk that the indiplon labeling granted by regulatory*

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*authorities may limit the commercial success of indiplon; and risk relating to market acceptance of indiplon following marketing approval. Specifically, the risks and uncertainties the Company faces with respect to the Company's drug discovery, pre-clinical and clinical development of products including, risk that the GnRH receptor antagonist, urocortin 2, CRF antagonist, Type-1 diabetes altered peptide ligand, and H1 antagonist clinical candidates will not proceed to later stage clinical trials; risk that in later stage clinical trials the Company's clinical candidates will fail to demonstrate that they are safe and/or efficacious in treating the targeted disease states; risk relating to the Company's dependence on contract manufacturers for clinical drug supply and compliance with regulatory requirements for marketing approval; risks associated with the Company's dependence on third parties for commercial manufacturing activities; 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, 2005. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.*

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