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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): September 12, 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 September 12, 2006, Neurocrine Biosciences, Inc. issued a press release to announce positive safety and efficacy results from a Phase II clinical trial using its proprietary, orally-active small molecule Gonadotropin-Releasing Hormone(GnRH) receptor antagonist (NBI-56418) and the discontinuation of the development of the APL-Diabetes program.

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

99.1 Press Release dated September 12, 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: September 12, 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 FROM FOLLOW-UP  
PHASE II STUDY WITH ITS ORALLY ACTIVE GnRH RECEPTOR  
ANTAGONIST IN ENDOMETRIOSIS**

**COMPANY ALSO REPORTED DISCONTINUATION OF APL DIABETES PROGRAM**

San Diego, CA, September 12, 2006 — Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced positive safety and efficacy results with completion of the second off-treatment 3-month period of its 6-month ‘proof of concept’, safety, efficacy and dose-finding Phase II clinical trial using its proprietary, orally-active small molecule Gonadotropin-Releasing Hormone (GnRH) receptor antagonist (NBI-56418). The Company previously reported positive preliminary results from the completion of the first 3-month double-blind period of this Phase II trial in April 2006.

While the primary endpoint of the study, reduction in the Composite Pelvic Sign and Symptoms Score (CPSSS) showed a greater than 5 point reduction in the higher dose group (150 mg), most striking was the reduction in the “worst pain” as measured by the Visual Analog Scale (VAS). The mean maximum score reported in the pre-treatment phase ranged from 63-73. These were reduced by an average of 13.1 (placebo), 25.8 (75 mg) and 37.4 (150 mg) during the third month on treatment. Pain reduction was reported within the first few weeks of treatment by some patients and benefits were also sustained for up to 12 weeks after discontinuation in many patients. Complete suppression of menses was only seen in a small subset of subjects.

“Now that the trial is complete, the data show that this oral GnRH antagonist reduces pain scores using several different standardized measures. More importantly, this first study in patients with endometriosis reveals that pain reduction may be achieved without profound suppression of estradiol or suppression of menses. If these findings are confirmed in subsequent clinical trials, women with endometriosis may one day be able to achieve pain control without suppression of menses and without high risk of bone loss,” said Chris O’Brien, M.D., Senior Vice President of Clinical Development for Neurocrine Biosciences.

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The study drug was generally well tolerated and adverse event rates show that there is little difference in the frequency of treatment emergent adverse events across treatment groups. The most common AEs reported during the first 3 months were nausea, headache and diarrhea and these were reported more frequently by recipients of the GnRH antagonist than the placebo. In contrast to GnRH agonists, there was no increase in hot flashes reporting by the NBI-56418 treated groups compared with placebo, menstrual cycles and ovulation were normal in the 3-month follow-up period off treatment. Plasma n-telopeptide, an important biomarker in assessing bone loss, was monitored and showed values remained in the normal range and most subjects had no change in n-telopeptide. There were no trends of treatment related changes in ECG or standard laboratory assessments.

#### **Study Design**

The 6-month data comes from a multi-center, randomized, double-blind, placebo-controlled trial involving patients with a confirmed diagnosis of endometriosis. The study followed a parallel-group design in which 76 subjects were randomized to one of three treatment groups: placebo, 75 mg of NBI-56418, or 150 mg of NBI-56418 each administered once daily. Dosing started on Day 2 to Day 7 of the menstrual cycle and continued over 12 weeks with assessments of symptoms and signs of disease conducted at 4-week intervals using the CPSSS. Assessment of pain intensity was measured daily by the VAS and collected by electronic diary. Patients were followed for 3 months on active treatment or placebo and for an additional post-treatment 3-month period to assess safety.

“We are pleased with these safety and efficacy results in the clinical setting over a long-term treatment period with our GnRH antagonist. Based on these data, we are moving ahead with an expanded six-month study in patients with endometriosis. This Phase IIb study will include several hundred patients and is expected to be initiated in the 4<sup>th</sup> Quarter of 2006,” said Wendell Wierenga Ph.D., Executive Vice President of Research and Development for Neurocrine Biosciences.

#### **Study Design for Additional Phase II Clinical Studies Underway with GnRH for Endometriosis**

Neurocrine is on track to initiate the Phase IIb study in the 4<sup>th</sup> quarter of 2006 in which patients with endometriosis will receive NBI-56418 for 6 months. In addition to confirming the effect of NBI-56418 on endometriotic pain, this study is designed primarily to assess the impact of longer treatment on bone mineral density as measured by DEXA scan. The 6-month results, together with data from an ongoing twice-daily dosing Phase II study initiated in December 2005 will be the basis for securing agreement to a registration plan acceptable to the FDA.

#### **Additional Phase II study in GnRH to be completed in the 4<sup>th</sup> Quarter of 2006**

Neurocrine has completed enrollment of patients in a second Phase II study in patients with endometriosis to explore once vs. twice daily dosing. This study, a multi-dose, double-blind, placebo-controlled trial, enrolled 68 patients and is designed to assess safety and efficacy over a 3-month period. The primary endpoint of reduction in endometriotic pain will be measured by the CPSSS and the VAS. Preliminary results are expected to be announced in the 4<sup>th</sup> Quarter of 2006.

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## **Background**

Nearly 7 million women in the US have endometriosis, many with severe or moderate symptoms. Many patients are believed to be misdiagnosed or undiagnosed. The impact of endometriosis on the lives of sufferers can be significant — adversely affecting the ability of patients to maintain relationships and employment.

Surgery and medical treatments are currently available for women with endometriosis. Surgery is not acceptable to many patients. Although indicated for endometriosis, medical therapies, such as the injectable GnRH agonist leuprolide or injectable progesterone, are associated with a range of potentially unacceptable side effects including bone loss. Consequently, prescribing physicians often reserve these medical interventions for patients with severe endometriosis. For the majority of endometriosis patients suffering from moderate or mild symptoms, the remaining treatment options, oral contraceptives and analgesics, are only partially effective.

## **APL Diabetes Program Discontinued**

Neurocrine also announced today that the results of its Phase II clinical trial using its altered peptide ligand (APL) technology for Type-1 diabetes did not meet its primary endpoint of preservation of C-peptide levels although the product was safe and well tolerated. The Phase II study was a dose-response, safety, tolerability and efficacy trial in approximately 188 adults/adolescents with new onset Type-1 diabetes. Based on these results, the Company has discontinued its APL program.

“While we are disappointed with the lack of efficacy for the APL diabetes program in the clinical setting, the primary objective of this program has always been ‘proof of concept’ before deploying large resources toward the APL program. The study was conducted efficiently and provided a clear signal to Neurocrine. We are fortunate to have a robust and diversified pipeline to bring forward other promising programs for development, with novel product candidates selected on an annual basis,” added Dr. Wierenga.

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 in general including the risks and uncertainties associated with, or arising out of, drug discovery, pre-clinical and clinical development of pharmaceutical products. Specifically, the Company faces risks and uncertainties arising out of its GnRH clinical development program including risk that its lead candidate, NBI-56418, will not proceed to later stage clinical trials; risk that should NBI-56418 may prove unsuitable for continued development, the Company will not be successful in identifying alternative GnRH antagonist products that are safe and effective; risk relating to the Company’s dependence on contract manufacturers for GnRH antagonist product clinical drug supply and compliance with regulatory requirements for marketing approval; risks that the Company may be dependent on corporate collaborators for commercial manufacturing and marketing and sales activities for its GnRH antagonist products; uncertainties relating to patent protection for the Company’s GnRH antagonist products 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 GnRH antagonist products; risk that the Company will be unable to raise additional funding required to complete development of its GnRH antagonist product candidates; and the other risks described in the Company’s report on Form 10-K for the year ended December 31, 2005 and report on Form 10-Q for the quarter ended June 30, 2006. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.*

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