## 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 28, 2005

# 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, San Diego, CA** (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)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4 (c))

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## ITEM 2.02 RESULTS OF OPERATION AND FINANCIAL CONDITION.

On April 28, 2005, Neurocrine Biosciences, Inc. announced its financial results for the quarter ended March 31, 2005. 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.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report of Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, ("Exchange Act") or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

#### ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(c) EXHIBITS. The following exhibit is filed herewith:

Exhibit Number	Description of Exhibit			
99.1	Press Release dated April 28, 2005			
	1			

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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: April 28, 2005 NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN

Paul W. Hawran Executive Vice President and Chief Financial Officer FOR IMMEDIATE RELEASE Contact at Neurocrine Biosciences Claudia Jones or Elizabeth Foster (858) 617-7600

#### NEUROCRINE BIOSCIENCES REPORTS FIRST QUARTER 2005 RESULTS

COMPANY WILL HOST A CONFERENCE CALL AND WEBCAST ON THURSDAY, APRIL 28
AT 4:30 PM EASTERN TIME

San Diego, CA, April 28, 2005 - Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended March 31, 2005. For the first quarter of 2005, the Company reported a net loss of \$18.8 million, or \$0.51 per share compared with a net loss of \$12.4 million, or \$0.35 per share, for the same period in 2004.

Revenues for the first quarter of 2005 were \$11.9 million compared with \$16.9 million for the same period last year. The decrease in revenues of \$5.0 million is primarily due to lower revenues recognized under our collaboration agreement with Pfizer, Inc. (Pfizer). During the first quarter of 2005, under the Pfizer collaboration agreement, the Company recognized \$4.0 million in the form of sponsored development funding and an additional \$5.4 million resulting from license fees. During the first quarter of 2004, the Company realized \$4.0 million from Pfizer for sponsored development funding and \$10.9 million resulting from license fees. Additionally, during the first quarter of 2005, the Company recognized \$1.0 million in revenue related to the commencement of its field sales force. During the first quarter of 2005, the Company also recognized a \$1.0 million milestone related to the successful completion of the research portion of the CRF antagonist collaboration with GlaxoSmithKline.

Research and development expenses decreased to \$25.6 million during the first quarter 2005 compared with \$26.4 million for the same period in 2004. The decrease in research and development expenses is primarily due to the indiplon Phase III program that is nearing completion, and was offset by increased research and development expenses in other programs.

Sales, general and administrative expenses increased to \$5.6 million for the first quarter 2005 compared with \$5.3 million during the same period last year. The increase in expenses from 2004 to 2005 primarily resulted from activities surrounding the implementation of our commercialization strategy, including commencing development of our sales force.

The Company's balance sheet on March 31, 2005 reflected total assets of \$486.4 million, including cash, cash equivalents, and marketable securities of \$270.9 million compared with balances at December 31, 2004 of \$519.2 million and \$301.1 million, respectively. The decrease in cash balances primarily resulted from the operating loss for the quarter and a decrease in accounts payable and accrued liabilities.

"In 2005 our efforts will be focused on supporting our sales and marketing infrastructure to support the co-detailing of Zoloft(R) with Pfizer and preparing for the launch and commercialization of indiplon as we continue our transition to a fully integrated pharmaceutical company," said Paul Hawran, Executive Vice President and Chief Financial Officer of Neurocrine Biosciences. "In addition, our R & D group has made significant progress in the past year in building and advancing our pipeline. We currently have six compounds in mid-to-late stage clinical development and expect to advance two additional research compounds into development this year," added Hawran.

#### R & D PIPELINE UPDATE

#### INDIPLON FOR INSOMNIA

Neurocrine announced on April 14, 2005 that the Company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for indiplon capsules for the treatment of insomnia in both adult and elderly patients. The NDA for indiplon tablets will be submitted also in the 2nd quarter of 2005.

Neurocrine has completed the initial phases of building the Neurocrine Sales and Marketing capabilities in preparation for the co-detailing of Zoloft(R) with Pfizer and for the indiplon launch. In 2005 Neurocrine hired 50% of its specialty sales force. The Company expects that its sales organization of 200 will be fully recruited, trained and deployed to commence co-detailing Zoloft(R) by the end of the 2nd quarter. All Zoloft product and sales training will be conducted by Pfizer.

#### GNRH ANTAGONISTS FOR WOMEN'S HEALTH DISORDERS

Neurocrine completed three Phase I single and multiple dose clinical studies with a GnRH antagonist candidate, NBI-56418 in approximately 50 healthy pre-menopausal women and in approximately 20 healthy males. Under single and multiple dosing, NBI-56418 demonstrated suppression of luteinizing hormone (LH) and estradiol in females, while single doses of NBI-56418 in males resulted in suppression of LH and testosterone. In all studies, NBI-56418 was shown to be safe and well tolerated. As a lead in to long term studies, including those designed to demonstrate efficacy, Neurocrine has completed enrollment in a six-week Phase I double-blind, multicenter, parallel group study of 42-day administration of two dose levels of NBI-56418 in an additional 60 healthy pre-menopausal women. Safety results demonstrated that NBI-56418 was safe and well tolerated. Preliminary efficacy results are consistent with previously reported studies demonstrating dose dependent estrogen suppression vs. placebo with once-a-day dosing. Based on these results, final doses have been selected for a 3-month Phase II study with NBI-56418 in endometriosis. This study was initiated in April of this year. Additionally, a back-up compound entered Phase I clinical trials in early October 2004.

#### UROCORTIN 2 FOR CONGESTIVE HEART FAILURE

Neurocrine is completing a series of Phase I clinical trials with a proprietary urocortin 2 compound to evaluate the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of urocortin 2 in healthy volunteers and has initiated a Phase IIa clinical study in patients with mild to moderate congestive heart failure in the 2nd Quarter of 2005. In preclinical efficacy and safety studies conducted by Neurocrine, urocortin 2 has shown positive hemodynamic effects, which may benefit patients with congestive heart failure.

Urocortin 2 was discovered in the laboratory of Neurocrine's co-founder, Dr. Wylie W. Vale, Professor and Head, Clayton Foundation for Research for Peptide Biology from the Salk Institute. Neurocrine licensed urocortin 2 from the Clayton Foundation for Research to further expand the Company's franchise in CRF research.

ALTERED PEPTIDE LIGAND (APL) FOR MULTIPLE SCLEROSIS (MS)

Neurocrine completed enrollment in a Phase II clinical trial with NBI-5788 in over 150 patients for the treatment of relapsing MS to evaluate the safety and tolerability of NBI-5788. The Phase II study was conducted at 28 sites in the US and Canada and was expanded to five Eastern European countries in 2004. Results are expected in early-2006.

#### ALTERED PEPTIDE LIGAND (APL) FOR TYPE 1 DIABETES

Neurocrine has successfully completed four Phase I/II clinical trials with NBI-6024 for Type 1 Diabetes. Additionally the Company has completed enrollment in a Phase II, dose-response, efficacy and safety trial in approximately 200 adults/adolescents with new onset Type 1 Diabetes. 30% of patients enrolled have completed a 2-year dosing regimen with no safety issues reported. Results are expected in mid-2006.

#### CRF FOR STRESS RELATED DISORDERS

The Corticotropin Releasing Factor (CRF) program (CRF small molecule antagonist) partnered with GlaxoSmithKline (GSK) has identified multiple unique preclinical compounds that are in various stages of development for anxiety, depression, and irritable bowel syndrome (IBS). Neurocrine and GSK are conducting a Phase I clinical trial with a lead CRF R1 receptor antagonist compound for anxiety and depression. The Phase I clinical trial is a double-blind, randomized, placebo controlled, single-dose study to evaluate the safety and pharmacokinetics (PK) of a range of escalating doses of this compound in healthy volunteers. Following completion of this initial Phase I clinical trial, the two companies will evaluate this lead compound in extended Phase I and Phase II proof of concept trials. In addition, a back-up compound is also expected to enter Phase I clinical trials in 2005.

#### MC-4 ANTAGONISTS FOR CACHEXIA

Neurocrine has selected a lead melanocortin-4 receptor (MC-4) antagonist compound for cachexia and will initiate Phase I clinical studies in the 3rd quarter of 2005.

#### ADDITIONAL RESEARCH PROGRAMS

Neurocrine's Research Department continues to advance novel small molecule compounds into clinical development. Neurocrine scientists are focusing on developing small molecule antagonists against G-protein coupled receptors (GPCRs).

- Advance lead MC-4 agonists are being optimized for the treatment of male erectile dysfunction and obesity.
- Advanced lead compounds from the melanin concentrating hormone (MCH) program are also being evaluated for development during 2005. MCH is believed to play an important role in the treatment of obesity, anxiety and depression.
- In addition, new orally active small molecule antagonists are being developed to treat various sleep disorders.

CONFERENCE CALL AND WEBCAST TODAY AT 4:30 PM EASTERN TIME
Neurocrine will also host a live conference call and Webcast to discuss its
first quarter financial results and provide a Company update Thursday afternoon,
April 28, 2005 at 4:30 PM Eastern Daylight Time (EDT) / 1:30 PM Pacific Daylight
Time (PDT). Participants may access the live Conference Call by dialing
1-800-905-0392 (U.S.) or 785-832-1508 (International) and using the Conference
ID# NBIX. The call can also be accessed via the Webcast through the Company's
website at http://www.neurocrine.com or alternatively through a link provided by
PRNewswire at: http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=
68817&eventID=1058115

If you are unable to attend the Webcast and would like further information on this announcement please contact Claudia Jones or Elizabeth Foster in the Investor Relations Department at Neurocrine Biosciences at (858) 617-7600. A replay of the Conference Call will be available approximately one hour after the conclusion of the call by dialing 1-800-723-0532 (US) or 402-220-2655 (International) and will be archived until Thursday, May 12, 2005.

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, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, 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 planned regulatory activities. Specifically, the risks and uncertainties the Company faces with respect to its indiplon program include, but are not limited to; risk that the Company will not be able to reformat the NDA for indiplon MR tablets within the Company's projected timelines; risk that the indiplon capsule and/or tablet NDAs as reformatted by the Company will not be acceptable to the FDA; the risk that regulatory authorities may reject our regulatory submissions or find them incomplete or insufficient; risk that additional clinical studies may be required to support submissions for regulatory approval; risk that the indiplon labeling granted by regulatory authorities may limit the commercial success of indiplon. 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 Company's CRF back-up, MC-4 and MCH research programs will not lead to viable clinical candidates, that the GnRH receptor antagonist, urocortin 2, CRF and altered peptide ligand clinical candidates will not proceed to later stage clinical trials; 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 corporate collaborators for commercial manufacturing and marketing and sales 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, 2004. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof. # # #

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# NEUROCRINE BIOSCIENCES, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (IN THOUSANDS, EXCEPT FOR LOSS PER SHARE DATA)

	Three Months Ended March 31,	
	2005	
	(unaudited)	(unaudited)
Revenues:		
Sponsored research and development License fees and milestones Sales force allowance Grant income	\$ 4,416 6,448 1,000	\$ 5,369 11,319  253
Total revenues	11,864	16,941
Operating expenses:    Research and development    Sales, general and administrative  Total operating expenses	25,603 5,608  31,211	26,388 5,283  31,671
Loss from operations Other income and (expenses):     Interest income     Interest expense	(19,347) 1,601 (1,084)	(14,730) 2,353
Total other income Loss before income tax expense Income tax expense	517 (18,830)	2,353 (12,377) 3
Net loss	\$(18,830)	
Net loss per common share: Basic and Diluted	====== \$ (0.51)	
Shares used in the calculation of net loss per common share: Basic and Diluted	36,598	35,527

# NEUROCRINE BIOSCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (IN THOUSANDS)

	March 31, 2005	December 31, 2004
	(unaudited)	
Cash, cash equivalents and marketable securities Other current assets	\$270,907 10,127	\$301,129 12,686
Total current assets	281,034	313,815
Property and equipment, net Prepaid royalties Other non-current assets	101,238 94,000 10,096	102,166 94,000 9,236
Total assets	\$486,368 ======	\$519,217 ======
Current liabilities Long-term liabilities Stockholders' equity	\$ 47,182 64,466 374,720	\$ 59,585 65,805 393,827
Total liabilities and stockholders' equity	\$486,368	\$519,217