

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): February 10, 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.)

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ITEM 2.02 RESULTS OF OPERATION AND FINANCIAL CONDITION.

On February 10, 2005, Neurocrine Biosciences, Inc. announced its financial results for the quarter ended December 31, 2004. 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 exhibits are filed herewith:

Exhibit Number	Description of Exhibit
99.1	Press Release dated February 10, 2005

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: February 10, 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
Elizabeth Foster or Claudia Jones
(858) 617-7600

**NEUROCRINE BIOSCIENCES REPORTS FOURTH QUARTER AND YEAR-END 2004
RESULTS**

San Diego, CA, February 10, 2005 — Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the fourth quarter and year ended December 31, 2004. For the three months ended December 31, 2004, the Company reported a net loss of \$20.6 million or \$0.57 loss per share compared to a net income of \$3.2 million or \$0.09 diluted earnings per share for the same period last year. For the year ended December 31, 2004, the Company had a net loss of \$45.8 million, or \$1.26 per share compared with a net loss of \$30.3 million, or \$0.93 per share in 2003. During 2003, the Company realized a one-time gain of \$18.0 million related to the sale of its previous corporate facility.

Revenues for the fourth quarter of 2004 were \$18.5 million compared with \$27.1 million for the same period last year. The decrease in revenues for the three months ended December 31, 2004 resulted primarily from reimbursement by Pfizer of clinical development expenses associated with the *indiplon* program of \$9.3 million down from \$13.6 million, for the same period in 2003. In addition, the Company recognized license fee revenues arising from the Pfizer collaboration of \$6.8 million and \$10.9 million during the same periods. Revenue earned under the GlaxoSmithKline (GSK) collaboration agreement was \$2.3 million for each period. During the fourth quarter of 2004, the Company received a \$1.0 million milestone from GSK for advancing its Corticotropin Releasing Factor (CRF) R₁ receptor antagonist into clinical trials.

Revenues for the year ended December 31, 2004, were \$85.2 million, compared with \$139.1 million for 2003. The decrease in revenues for the year ended December 31, 2004 resulted primarily from lower sponsored development revenue associated with the winding down of the *indiplon* clinical development program of \$21.7 million versus \$90.9 million for 2003. This decrease was offset by milestones, totaling \$20.5 million, achieved during 2004 under the Pfizer collaboration agreement related to successful Phase III clinical trials for long-term administration and sleep maintenance of *indiplon*. In addition, the Company recognized license fee revenues of \$34.8 million in 2004 versus \$38.0 million in 2003 arising from the Pfizer collaboration.

Research and development expenses decreased by \$5.7 million to \$33.4 million for the fourth quarter of 2004 compared with \$39.1 million for the same period in 2003, primarily resulting from winding down of the Phase III *indiplon* program and offset by increased personnel, laboratory costs and external development costs in other programs. For the year ended December 31, 2004, research and development expenses were \$115.1 million compared to \$177.3 million last year. This \$62.2 million decrease in year-to-date research and development expenses are a result of the items mentioned above.

General and administrative expenses were \$6.3 million for the fourth quarter 2004 compared with \$5.4 million for the same period in 2003. For the year ended December 31, 2004 general and administrative expenditures totaled \$22.4 million compared to \$20.6 million in 2003. The increase in general and administrative expenses primarily resulted from the addition of

administrative personnel needed to support expanding research and development activities and implementation of our commercialization strategy.

The Company's balance sheet at December 31, 2004 reflected total assets of \$519.2 million including cash, cash equivalents, marketable securities and current assets of \$313.8 million, compared with balances at December 31, 2003 of \$555.0 million and \$471.8 million, respectively. The decrease in current asset balances at December 31, 2004 primarily resulted from the purchase of the *indiplon* royalty stream for \$50.0 million, a \$32.8 million decrease in payables related to clinical trials and our net loss of \$45.8 million.

"2005 will be a year of accelerated growth for Neurocrine. We will focus on building our commercial organization and preparing for the launch of *indiplon*. In late 2004, we commenced the hiring of our sales force to co-detail Zolof[®] beginning in May 2005 with our partner Pfizer. We are also proud of our continuing development pipeline with six additional compounds in clinical development including two GnRH compounds for women's disorders, APL compounds for MS and diabetes, CRF for anxiety and depression, and urocortin 2 for congestive heart failure. We look forward to announcing the progress of these trials throughout the year," said Paul Hawran, Executive Vice President and Chief Financial Officer of Neurocrine Biosciences.

"We recently announced that we will resubmit our NDA for *indiplon* immediate release at the end of the 1st Quarter/beginning of the 2nd Quarter, followed by the modified release NDA also in the 2nd Quarter of 2005. Based on the resubmissions of the *indiplon* NDAs we are now expecting a loss of approximately \$35 to \$40 million in 2005 and expect profitability in 2006 upon the commercialization of *indiplon*," added Hawran.

A Year In Review

- Reported positive results from 5 Phase III clinical trials with *indiplon* in 2004, having completed 68 clinical trials overall for *indiplon* immediate release capsules and modified release tablets;
 - Advancing six compounds further in clinical development, in addition to *indiplon*;
 - Two new proprietary compounds selected for INDs;
 - Completed enrollment in a 42-day Phase I trial with a Gonadotropin-Releasing Hormone (GnRH) antagonist back-up compound with no safety issues. 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 the doses have been selected for a 3-month Phase II study in patients with endometriosis to begin in the 2nd Quarter of 2005.
 - Also reported positive Phase I multiple-dose results with a second-generation GnRH antagonist compound for the treatment of endometriosis.
 - Completed enrollment in a Phase II clinical trial with NBI-5788 for Multiple Sclerosis with an increased number of patients. Results are expected in early-2006.
 - Also completed enrollment in a Phase II clinical trial with NBI-6024 for Type 1 diabetes. Interim results will be released in 3rd Quarter 2005 and final results in early-2006.
 - Completing Phase I clinical trials with urocortin 2, being developed for the treatment of acute congestive heart failure (CHF), with positive preliminary efficacy results. A Phase II trial in CHF patients will begin in mid-2005.
 - Initiated Phase I clinical development with partner GSK for Corticotropin Releasing Factor (CRF) R₁ receptor antagonists for anxiety and depression.
 - In-licensed A2A receptor antagonists for development for Parkinson's disease.
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R & D Pipeline Update

Indiplon for Insomnia

Neurocrine will announce results from clinical study 404 with *indiplon* modified release in adults with chronic insomnia in mid-February 2005. To date Neurocrine has completed its registration program for *indiplon*, which comprises one of the most extensive programs conducted to date in insomnia, with data from 68 clinical trials and over 80 preclinical studies and includes a comprehensive safety and efficacy evaluation in over 7500 subjects.

GnRH Antagonists for Women's Health Disorders

Neurocrine completed three Phase I single and multiple dose clinical studies with the second generation 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 leutenizing 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 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 the doses have been selected for a 3-month Phase II study with NBI-56418 in endometriosis, which is expected to be initiated in the 2nd Quarter of 2005. Additionally a back-up compound entered Phase I clinical trials in early October 2004.

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). In December 2004, Neurocrine and GSK initiated 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.

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 expects to initiate a Phase II clinical study in patients with mild to moderate congestive heart failure in the 2nd Quarter of 2005. Urocortin 2 has a novel mechanism of action. In preclinical efficacy and safety studies conducted by Neurocrine, urocortin 2 has demonstrated positive hemodynamic effects on cardiac output and blood pressure, 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 I Diabetes

Neurocrine has successfully completed four Phase I/II clinical trials with NBI-6024 for Type I 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. Interim results from this trial are expected in the 3rd Quarter of 2005 and final results in early-2006.

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). In addition, in November 2004 Neurocrine in-licensed A2A receptor antagonists for Parkinson's disease from Almirall Prodesfarma, S.A., the leading Spanish Multinational Pharmaceutical Company. The compounds are selective small molecule A2A receptor antagonists that have shown efficacy in preclinical models of Parkinson's disease. A2A is a subtype of receptors for the neuromodulator adenosine. Preclinical and clinical studies have demonstrated that selective A2A receptor antagonists relieve Parkinson's symptoms as monotherapy and, when given in combination with the standard treatment L-DOPA, can augment the beneficial effects of this therapy.

Neurocrine expects to select one or more compounds for clinical development during 2005.

Advanced research compounds will be selected from the following programs:

- A development compound from the melanocortin-4 receptor (MC-4) technology is expected to begin clinical studies in mid-2005. MC-4 represents a novel target for the treatment of obesity, cachexia, and pain.
- Advanced lead compounds are also being evaluated from the melanin concentrating hormone (MCH) technology. MCH is believed to play an important role in the treatment of obesity, anxiety and depression. Neurocrine expects to advance a development candidate into toxicology studies in 2005.
- 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 year-end results and provide a Company update today, Thursday afternoon, February 10, 2005 at 4:30 PM Eastern Standard Time (EST) / 1:30 PM Pacific Standard Time (PST). The live Conference Call can be accessed by dialing 1-800-905-0392 (U.S.) or 785-832-0201 (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=1011381>

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 by dialing 1-800-839-3607 (US) or 402-220-2970 (International) and will be archived until Thursday, February 24, 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 indiplon IR and/or MR NDA within the Company's projected timelines; risk that the Company will be unable to reformat the indiplon IR and/or MR NDA in a manner 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 risk and uncertainties associated with, or arising out of, drug discovery, pre-clinical and clinical development of products including risk that the Company's CRF, MC-4, MCH, A2A receptor antagonist and sleep research programs will not lead to viable clinical candidates, that the GnRH receptor antagonist, urocortin 2 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, 2003 and most recent report on Form 10-Q filed for the quarter ended, September 30, 2004. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

NEUROCRINE BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations
(in thousands except for income (loss) per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2004 (unaudited)	2003	2004 (unaudited)	2003
Revenues:				
Sponsored research and development	\$ 10,676	\$ 15,048	\$ 27,156	\$ 96,699
License fees and milestones	7,809	11,820	57,612	41,126
Grant income	—	267	408	1,253
Total revenues	<u>18,485</u>	<u>27,135</u>	<u>85,176</u>	<u>139,078</u>
Operating expenses:				
Research and development	33,404	39,087	115,066	177,271
General and administrative	6,265	5,419	22,444	20,594
Total operating expenses	<u>39,669</u>	<u>44,506</u>	<u>137,510</u>	<u>197,865</u>
Loss from operations	(21,184)	(17,371)	(52,334)	(58,787)
Other income and (expenses):				
Gain on sale of property	—	17,946	—	17,946
Interest income and expense, net	783	2,601	6,775	10,601
Other income and expense, net	(214)	17	(214)	(16)
Total other income	<u>569</u>	<u>20,564</u>	<u>6,561</u>	<u>28,531</u>
Net income (loss)	<u>\$ (20,615)</u>	<u>\$ 3,193</u>	<u>\$ (45,773)</u>	<u>\$ (30,256)</u>
Net income (loss) per common share:				
Basic and diluted	<u>\$ (0.57)</u>	<u>\$ 0.09</u>	<u>\$ (1.26)</u>	<u>\$ (0.93)</u>
Shares used in the calculation of income (loss) per common share:				
Basic	<u>36,477</u>	<u>35,273</u>	<u>36,201</u>	<u>32,374</u>
Diluted	<u>36,477</u>	<u>37,459</u>	<u>36,201</u>	<u>32,374</u>

NEUROCRINE BIOSCIENCES, INC.
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2004 (unaudited)	December 31, 2003
Cash, cash equivalents and marketable securities	\$ 301,129	\$ 453,168
Other current assets	12,686	18,641
Total current assets	<u>313,815</u>	<u>471,809</u>
Property and equipment, net	102,166	56,236
Prepaid royalty	94,000	—
Other non-current assets	9,236	26,910
Total assets	<u>\$ 519,217</u>	<u>\$ 554,955</u>
Current liabilities	\$ 59,585	\$ 110,012
Long-term liabilities	65,805	53,823
Stockholders' equity	393,827	391,120
Total liabilities and stockholders' equity	<u>\$ 519,217</u>	<u>\$ 554,955</u>