
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): August 3, 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)
 - 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 2.02 RESULTS OF OPERATION AND FINANCIAL CONDITION.

On August 3, 2005, Neurocrine Biosciences, Inc. announced its financial results for the quarter ended June 30, 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 August 3, 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: August 3, 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-Woodworth
(858) 617-7600

NEUROCRINE BIOSCIENCES REPORTS SECOND QUARTER 2005 RESULTS

San Diego, CA, August 3, 2005 — Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended June 30, 2005. For the second quarter, the Company reported a net loss of \$5.6 million, or \$0.15 per share compared with a net loss of \$11.1 million, or \$0.31 per share, for the same period last year. For the six months, the Company reported a net loss of \$24.4 million, or \$0.67 per share, as compared to \$23.5 million, or \$0.65 per share, for the same period last year.

Revenues for the second quarter of 2005 were \$33.2 million compared with \$15.0 million for the respective period last year. Revenues for the six months ended June 30, 2005 were \$45.0 million compared with \$32.0 million for the same period in 2004. The increase in revenues for the three and six month periods is primarily due to achievement of a \$20.0 million milestone under the Pfizer agreement related to the acceptance for review of the New Drug Application (NDA) filing for *indiplon* capsules by the U.S. Food and Drug Administration. Additionally, sponsored development revenue associated with the *indiplon* clinical program increased compared to last year. During 2005, the Company recognized \$2.7 million and \$6.7 million, for the three and six months ended June 30, 2005 in the form of sponsored development funding under the Pfizer collaboration agreement compared to \$1.1 million and \$5.1 million for the three and six months ended June 30, 2004. License fees, milestones and sales force allowance recognized under the Pfizer collaboration were \$30.4 million and \$36.9 million for the three and six months ended June 30, 2005 and \$11.5 million and \$22.5 million for the three and six months ended June 30, 2004.

Research and development expenses increased to \$29.6 million for the second quarter of 2005 from \$23.0 million for the respective period in 2004. For the six months ended June 30, 2005, research and development expenses were \$55.2 million compared to \$49.4 million for the same period last year. This increase in expenses primarily reflect increased personnel and laboratory costs, as well as external development costs related to the GnRH, Urocortin 2 and Multiple Sclerosis programs.

Sales, general and administrative expenses increased to \$9.8 million for the second quarter of 2005 compared with \$5.5 million during the same period last year. For the six months ended June 30, 2005, sales, general and administrative expenses were \$15.4 million compared to \$10.8 million for the respective period in 2004. The increase in expenses from 2004 to 2005 resulted primarily from activities surrounding the implementation of the commercialization strategy, including hiring and training the 200 person sales force. Sales force costs are largely reimbursed by Pfizer.

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The Company's balance sheet on June 30, 2005 reflected total assets of \$475.5 million, including cash, cash equivalents, marketable securities, and receivables due under the collaboration agreement of \$266.1 million as compared with balances at December 31, 2004 of \$519.2 million and \$309.3 million, respectively.

R & D Pipeline Update

Indiplon for Insomnia

Neurocrine announced recently that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA)s for *indiplon capsules* and *tablets* for review for the treatment of insomnia in both adult and elderly patients.

Neurocrine's sales force has commenced the co-detailing of Zoloft[®] with Pfizer in the second quarter of 2005. The Company's psychiatric specialty sales force of 200 has been fully recruited, trained and deployed. All Zoloft[®] product and sales training was conducted by Pfizer. Neurocrine's Sales and Marketing organization is actively preparing for the launch of *indiplon*.

Neurocrine presented four abstracts at the recent American Psychiatric Association (APA) and the Associated Professional Sleep Societies (APSS) Annual Meetings. Highlights of the meetings included data that showed that nightly administration of *indiplon* resulted in significant and sustained improvement in sleep onset and sleep maintenance in patients with chronic insomnia over the entire treatment period. Data also showed there was no evidence of tolerance over three months or withdrawal upon discontinuation of treatment – complications often seen with extended use of older-generation sleep medications. The results of several studies presented showed that *indiplon capsules and tablets* safely and effectively help elderly patients with chronic insomnia fall asleep faster and stay asleep throughout the night.

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 premenopausal 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. In preparation of long term studies, including those designed to demonstrate efficacy, Neurocrine 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 premenopausal women. Safety results demonstrated that NBI-56418 was safe and well tolerated. Preliminary efficacy results were consistent with previously reported studies demonstrating dose dependent estrogen suppression vs. placebo with once-a-day dosing. Based on these results, final doses were 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 will enter Phase I in the third quarter this year.

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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. In the second quarter of 2005, Neurocrine initiated a Phase IIa clinical study in patients with mild to moderate congestive heart failure. This later study is expected to be completed in the third quarter of 2005. The Company anticipates data in the third quarter at which time the Company plans to file an IND to initiate a trial in patients with stable congestive heart failure.

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 is being 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. Results for all patients enrolled 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 Phase I clinical trials with a lead CRF R₁ receptor antagonist compound for anxiety and depression. The Phase I clinical trial includes double-blind, randomized, placebo controlled, single-dose studies followed by multiple dose studies to evaluate the safety and pharmacokinetics (PK) of a range of escalating doses of this compound in healthy volunteers. Following completion of these clinical trials, 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.

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).

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- MC-4 agonists are being optimized for the treatment of male erectile dysfunction and obesity and antagonists for the treatment of cachexia.
- In addition, new orally active small molecule antagonists are being developed to treat various sleep disorders.
- Neurocrine scientists are also developing A2A antagonists for Parkinson's disease.

Conference Call and Webcast Today at 4:30 PM Eastern Time

Neurocrine will also host a live conference call and Webcast to discuss its second quarter financial results and provide a Company update Wednesday afternoon, August 3, 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 1-800-540-0559 (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>

If you are unable to attend the Webcast and would like further information on this announcement please contact Claudia Jones-Woodworth 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 1-888-562-2815 (US) or 402-220-7352 (International) and will be archived until Wednesday, August 17, 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 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 that the indiplon labeling granted by regulatory 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 Company's CRF back-up, A2A antagonists and MC-4 research programs will not lead to viable clinical candidates, risk

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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 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, 2004 and most recent report on Form 10-Q filed for the quarter ended, June 30, 2005. 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 June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(unaudited)		(unaudited)	
Revenues:				
Sponsored research and development	\$ 2,721	\$ 2,506	\$ 7,137	\$ 7,875
License fees and milestones	25,448	12,388	31,896	23,707
Sales force allowance	5,000	—	6,000	—
Grant income	—	155	—	408
Total revenues	<u>33,169</u>	<u>15,049</u>	<u>45,033</u>	<u>31,990</u>
Operating expenses:				
Research and development	29,633	22,969	55,236	49,357
Sales, general and administrative	9,788	5,469	15,396	10,752
Total operating expenses	<u>39,421</u>	<u>28,438</u>	<u>70,632</u>	<u>60,109</u>
Loss from operations	(6,252)	(13,389)	(25,599)	(28,119)
Other income and (expenses):				
Interest income and expense, net	659	2,259	1,176	4,612
Other income and (expense), net	(11)	(1)	(11)	(4)
Total other income	<u>648</u>	<u>2,258</u>	<u>1,165</u>	<u>4,608</u>
Net loss	<u>\$ (5,604)</u>	<u>\$ (11,131)</u>	<u>\$ (24,434)</u>	<u>\$ (23,511)</u>
Net loss per common share:				
Basic and diluted	\$ (0.15)	\$ (0.31)	\$ (0.67)	\$ (0.65)
Shares used in the calculation of net loss per common share:				
Basic and diluted	36,647	36,368	36,623	35,947

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

	June 30, 2005 (unaudited)	December 31, 2004
Cash, cash equivalents and marketable securities	\$ 243,268	\$ 301,129
Other current assets	28,257	12,686
Total current assets	<u>271,525</u>	<u>313,815</u>
Property and equipment, net	99,811	102,166
Prepaid royalty	94,000	94,000
Other non-current assets	10,176	9,236
Total assets	<u>\$ 475,512</u>	<u>\$ 519,217</u>
Current liabilities	\$ 40,294	\$ 59,585
Long-term liabilities	63,199	65,805
Stockholders' equity	<u>372,019</u>	<u>393,827</u>
Total liabilities and stockholders' equity	<u>\$ 475,512</u>	<u>\$ 519,217</u>