
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): October 24, 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 October 24, 2005, Neurocrine Biosciences, Inc. announced its financial results for the quarter ended September 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 October 24, 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: October 24, 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 Woodworth
(858) 617-7600

NEUROCRINE BIOSCIENCES REPORTS THIRD QUARTER 2005 RESULTS

San Diego, CA, October 24, 2005 — Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended September 30, 2005. For the third quarter of 2005, the Company reported net income of \$26.2 million, or \$0.71 basic earnings per share compared to a net loss of \$1.6 million, or \$0.05 loss per share, for the same period last year. For the nine months ended September 30, 2005, the Company reported net income of \$1.7 million, or \$0.05 basic earnings per share compared to a net loss of \$25.2 million, or \$0.70 loss per share, for the same period last year.

Revenues for the third quarter of 2005 were \$64.7 million compared with \$34.7 million for the respective period last year. Revenues for the nine months ended September 30, 2005 were \$109.8 million compared with \$66.7 million for the same period in 2004. The increase in revenues for the three and nine month periods is primarily due to achievement of a \$50.0 million milestone under the Pfizer agreement related to the acceptance for review of the New Drug Application filing for *indiplon* tablets by the U.S. Food and Drug Administration. Sponsored development associated with the *indiplon* clinical program decreased compared to last year. During 2005, the Company recognized \$1.3 million and \$7.9 million, for the three and nine months ended September 30, 2005 in the form of sponsored development funding under the Pfizer collaboration agreement compared to \$7.3 million and \$12.3 million for the three and nine months ended September 30, 2004. License fees and milestones recognized under the Pfizer collaboration were \$55.4 million and \$86.3 million for the three and nine months ended September 30, 2005 and \$26.1 million and \$48.5 million for the three and nine months ended September 30, 2004. The sales force allowance earned under the Pfizer collaboration agreement was \$8.0 million and \$14.0 million for the three and nine months ended September 30, 2005.

Research and development expenses decreased to \$26.6 million for the third quarter of 2005 from \$32.3 million for the respective period in 2004. For the nine months ended September 30, 2005 and 2004, research and development expenses were \$81.9 million and \$81.7 million, respectively. This decrease in research and development expenses during the third quarter primarily reflects lower costs associated with the *indiplon* development program.

Sales, general and administrative expenses increased to \$13.0 million for the third quarter of 2005 compared with \$5.4 million during the same period last year. For the nine months ended September 30, 2005, sales, general and administrative expenses were \$28.4 million compared to \$16.2 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, training and deploying the 200 person sales force. Sales force costs are largely reimbursed by Pfizer.

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The Company's balance sheet on September 30, 2005 reflected total assets of \$501.0 million, including cash, cash equivalents, marketable securities, and receivables due under collaboration agreements of \$292.4 million as compared with balances at December 31, 2004 of \$519.2 million and \$309.3 million, respectively.

Financial Guidance

The financial guidance for the year ending 2005 has adjusted the loss to approximately \$25 million from a previously anticipated loss of \$30 to \$35 million. The reduced loss results primarily from lower than expected external development expenses and anticipated milestones from the company's collaboration with GlaxoSmithKline.

Sales Force of 200 Now Fully Operational

The U.S. sales organization of 200 has been fully recruited, trained by Pfizer, and is now deployed in the field. The sales team is co-detailing Zoloft to 25,000 psychiatrists. The sales force reach and call frequency are exceeding target projections with over 70,000 calls made to date on the target audiences.

Indiplon for Insomnia

The U.S. Food and Drug Administration (FDA) has accepted and is currently reviewing the Company's New Drug Applications for *indiplon* capsules and tablets for the treatment of insomnia in both adult and elderly patients. PDUFA action dates for the capsules and tablets are in the first quarter of 2006.

Driving Study Preliminary Results

Neurocrine recently completed a randomized, double-blind, active- and placebo-controlled, four-way crossover, out-patient clinical trial conducted in 30 healthy volunteers to measure the impairment on next day driving performance after nighttime administration of *indiplon* 10mg, and 15mg, zopiclone 7.5mg or placebo. Following nighttime administration of *indiplon* there was no statistical difference for either *indiplon* dose vs. placebo on measurements of driving performance in a simulator, the primary endpoint in the study. These preliminary results also showed that zopiclone exhibited statistically significant impairment on driving performance. Safety results with *indiplon* were consistent with those previously reported in studies with *indiplon* 10mg and 15mg.

GnRH Antagonists for Women's Health Disorders

The company has initiated a three month Phase II study in endometriosis. Enrollment is expected to be completed in November 2005 with results available in early 2006.

A second Phase II study in endometriosis is expected to be initiated in the fourth quarter of this year to more fully explore dose response, in anticipation of beginning six month studies in the second half of 2006. We also anticipate filing an Investigational New Drug (IND) in the fourth quarter to initiate Phase I Benign Prostatic Hyperplasia (BPH) studies in males as a basis for a Phase II study during 2006. Additionally, a back-up compound entered Phase I endometriosis studies in October 2005.

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Urocortin 2 for Congestive Heart Failure (CHF)

The Company completed dosing in a Phase IIa clinical study in patients with mild to moderate CHF in the third quarter of 2005. Results from this study are expected in the fourth quarter of 2005, at which time we expect to file an IND in the US for Phase II dose exploration studies in CHF patients.

Altered Peptide Ligand (APL) for Multiple Sclerosis (MS)

Results are expected in early 2006 from a Phase II clinical trial with NBI-5788 involving over 150 patients for the treatment of relapsing MS. The study will evaluate safety and tolerability. 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.

Altered Peptide Ligand (APL) for Type 1 Diabetes

Neurocrine has completed enrollment in a Phase II, dose-response, efficacy and safety trial in approximately 190 adults/adolescents with new onset Type 1 Diabetes. Results for all patients enrolled are expected in mid-2006.

Corticotropin Releasing Factor (CRF) for Stress Related Disorders

The 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). A lead CRF R₁ receptor antagonist compound is expected to complete Phase I in 2006. The Phase I program includes double-blind, randomized, placebo controlled, single-dose studies followed by multiple dose studies to evaluate the safety/tolerability and PK of a range of escalating doses of this compound in healthy volunteers. On successful completion of Phase I, Phase II clinical trials in IBS are expected to begin in early 2006 with depression/anxiety studies starting in mid-2006.

Additional Compound for Insomnia To Enter Clinical Development

Neurocrine will file an IND in the fourth quarter of 2005 for the evaluation of safety and efficacy of a new compound, NBI-75043, for the treatment of insomnia. NBI-75043 is an orally active, highly selective and short acting agent that, in preclinical studies, has demonstrated safety and efficacy for the treatment of various sleep disorders. Phase I studies will evaluate the safety and PK of single and multiple doses as well as selective sleep-related parameters.

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. In addition, 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 third quarter financial results and provide a Company update Monday afternoon, October 24, 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 785-832-0326 (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>

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If you are unable to attend the Webcast and would like further information on this announcement please contact Claudia 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 1-800-839-3607 (US) or 402-220-2970 (International) and will be archived until Monday, November 7, 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 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, September 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 per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
	(unaudited)		(unaudited)	
Revenues:				
Sponsored research and development	\$ 1,297	\$ 8,605	\$ 8,434	\$ 16,480
License fees and milestones	55,448	26,096	87,344	49,803
Sales force allowance	8,000	—	14,000	—
Grant income	—	—	—	408
Total revenues	<u>64,745</u>	<u>34,701</u>	<u>109,778</u>	<u>66,691</u>
Operating expenses:				
Research and development	26,627	32,305	81,863	81,662
Sales, general and administrative	12,997	5,427	28,393	16,179
Total operating expenses	<u>39,624</u>	<u>37,732</u>	<u>110,256</u>	<u>97,841</u>
Income (loss) from operations	25,121	(3,031)	(478)	(31,150)
Other income and (expenses):				
Interest income and expense, net	1,056	1,384	2,232	5,992
Other income and (expense), net	(26)	—	(37)	—
Total other income	<u>1,030</u>	<u>1,384</u>	<u>2,195</u>	<u>5,992</u>
Net income (loss)	<u>\$ 26,151</u>	<u>\$ (1,647)</u>	<u>\$ 1,717</u>	<u>\$ (25,158)</u>
Net income (loss) per common share:				
Basic	\$ 0.71	\$ (0.05)	\$ 0.05	\$ (0.70)
Diluted	\$ 0.68	\$ (0.05)	\$ 0.05	\$ (0.70)
Shares used in the calculation of net income (loss) per common share:				
Basic	36,707	36,427	36,685	36,108
Diluted	38,406	36,427	37,992	36,108

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

	September 30, 2005	December 31, 2004
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 290,838	\$ 301,129
Other current assets	6,790	12,686
Total current assets	<u>297,628</u>	<u>313,815</u>
Property and equipment, net	98,937	102,166
Prepaid royalty	94,000	94,000
Other non-current assets	10,404	9,236
Total assets	<u>\$ 500,969</u>	<u>\$ 519,217</u>
Current liabilities	\$ 35,039	\$ 59,585
Long-term liabilities	62,190	65,805
Stockholders' equity	403,740	393,827
Total liabilities and stockholders' equity	<u>\$ 500,969</u>	<u>\$ 519,217</u>