Table of Contents

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): January 23, 2006

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-22705**	**33-0525145**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(IRS Employer Identification No.)

12790 El Camino Real, San Diego, CA	**92130**
(Address of principal executive offices)	(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:

o 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))

TABLE OF CONTENTS

ITEM 2.02 RESULTS OF OPERATION AND FINANCIAL CONDITION..
ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.
SIGNATURES
EXHIBIT 99.1

Table of Contents

ITEM 2.02 RESULTS OF OPERATION AND FINANCIAL CONDITION.

On January 23, 2006, Neurocrine Biosciences, Inc. announced its financial results for the year and quarter ended December 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 January 23, 2006

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: January 23, 2006

NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN
Paul W. Hawran
Executive Vice President
and Chief Financial Officer

EXHIBIT 99.1

FOR IMMEDIATE RELEASE
Contact at Neurocrine Biosciences
Elizabeth Foster or ClaudiaWoodworth
(858) 617-7600

NEUROCRINE BIOSCIENCES REPORTS FOURTH QUARTER AND YEAR-END 2005 RESULTS

San Diego, CA, January 23, 2006 — Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the fourth quarter and year ended December 31, 2005. For the three months ended December 31, 2005, the Company reported a net loss of $23.9 million or $0.65 loss per share compared to a net loss of $20.6 million or $0.57 loss per share for the same period last year. For the year ended December 31, 2005, the Company had a net loss of $22.2 million, or $0.60 loss per share compared with a net loss of $45.8 million, or $1.26 loss per share in 2004.

Revenues for the fourth quarter of 2005 were $14.1 million compared with $18.5 million for the same period last year. The decrease in revenues for the three months ended December 31, 2005 resulted primarily from reimbursement by Pfizer of clinical development expenses associated with the *indiplon* program of $0.8 million in the fourth quarter of 2005 down from $9.3 million, for the same period in 2004. In addition, the Company recognized license fee revenues arising from the Pfizer collaboration of $4.4 million and $6.8 million during the fourth quarter of 2005 and 2004, respectively. The sales force allowance earned under the collaboration agreement was $8.0 million for the fourth quarter of 2005. Revenue milestones related to CRF drug candidate development earned under the GlaxoSmithKline (GSK) agreement were $1.0 million for each period.

Revenues for the year ended December 31, 2005, were $123.9 million, compared with $85.2 million for 2004. The increase in revenues for the year ended December 31, 2005 resulted primarily from the achievement of $70.0 million in milestones under the Pfizer agreement related to acceptance for review of the New Drug Application (NDA) filing for *indiplon* tablets and capsules by the U.S. Food and Drug Administration. During 2005, the Company recognized $8.7 million in the form of sponsored development funding under the Pfizer collaboration agreement compared to $21.7 million for the year ended December 31, 2004. License fees and milestones recognized under the Pfizer collaboration were $90.7 million for the year ended December 31, 2005 and $55.3 million for the year ended December 31, 2004. The sales force allowance earned under the collaboration agreement was $22.0 million for 2005. The Company also recognized milestones under the GSK collaboration agreement of $2.0 million during 2005.

Research and development expenses decreased by $8.6 million to $24.8 million for the fourth quarter of 2005 compared with $33.4 million for the same period in 2004, 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, 2005, research and development expenses were $106.6 million compared to $115.1 million last year. This $8.5 million decrease in year-to-date research and development expenses are a result of the wind down of the Phase III *indiplon* clinical program.

Sales, general and administrative expenses were $13.9 million for the fourth quarter 2005 compared with $6.3 million for the same period in 2004. For the year ended December 31, 2005

sales, general and administrative expenditures totaled $42.3 million compared to $22.4 million 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.

The Company's balance sheet at December 31, 2005 reflected total assets of $483.1 million including cash, cash equivalents, marketable securities and current assets of $279.3 million, compared with balances at December 31, 2004 of $519.2 million and $313.8 million, respectively.

Financial Guidance for 2006
Financial guidance for 2006 excludes the impact associated with *indiplon* sales and subsequent net royalty revenues but includes the milestones associated with approval. The Company will revise and update the financial guidance at the time of *indiplon* launch to provide forecasted sales and the associated royalty revenues. Accordingly, the Company is forecasting total revenues in 2006 of $165.0 million to $175.0 million, excluding royalties from *indiplon* sales, and total operating expenses of $170.0 million to $180.0 million, which includes approximately $18.0 million relating to FAS 123R expense. After including other income of approximately $5.0 million, the Company is projecting a breakeven to net loss of approximately $10.0 million, before any net royalties associated with sales of *indiplon*.

Organizational Change
To reflect the growing importance of business development and alliance management to the future of Neurocrine, Kevin Gorman has been promoted from Senior Vice President, Business Development to Executive Vice President & Chief Business Officer. Kevin Gorman will be responsible for business development, alliance management and strategic planning.

***Indiplon* for Insomnia**
The U.S. Food and Drug Administration (FDA) 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. As announced earlier this month, the FDA has requested submission of results from the driving study completed in late 2005. Based on feedback from the FDA, the Company anticipates labeling that includes data from this study. To complete review of the driving study and a combined package insert, the FDA has advised that the PDUFA dates for the capsules and tablets have been adapted accordingly to May 15, 2006 and June 27, 2006 respectively. However, the FDA has committed to an action by May 15, 2006 for both NDAs. In addition, the Drug and Enforcement Administration (DEA) will work to complete its scheduling process in parallel with the FDA process. The Company is moving forward with full commercialization as planned.

R & D Pipeline Update
GnRH Antagonists for Women's Health Disorders
Enrollment has been completed in a three month Phase II study with NBI-56418 in 76 patients with endometriosis. The primary endpoint of the study is reduction in endometriotic pain as measured with the Composite Pelvic Sign and Symptoms Score (CPSSS), a validated clinical endpoint. Results from the 12-week, double-blind, placebo-controlled study are expected to be announced in April 2006.

A second Phase II study in patients with endometriosis was initiated in December 2005 to more fully explore dose response. The study is enrolling 72 patients and is designed to assess safety and efficacy over a three month period. The primary endpoint is reduction in endometriotic pain as measured by CPSSS. Preliminary results are expected to be announced in the 3rd Quarter of 2006.

Neurocrine filed a separate GnRH Investigational New Drug (IND) application in the fourth quarter of 2005 to initiate Phase I studies in males for the treatment of Benign Prostatic Hyperplasia (BPH). These Phase I studies in males will serve as the basis for a Phase II program assessing NBI-56418 as treatment for BPH beginning in the second half of 2006.

Urocortin 2 for Congestive Heart Failure
Neurocrine recently reported positive safety and efficacy results from the Company's Phase IIa clinical trial of urocortin 2 (NBI-69734) in patients with mild to moderate congestive heart failure (CHF). The Phase IIa trial was a single-blind, placebo-controlled, dose-escalation study to evaluate the safety, pharmacokinetic and pharmacodynamic characteristics of two doses of urocortin 2 in patients with stable CHF. Patients were administered single one-hour infusions of placebo and two doses of urocortin 2 over a four-week period. Results demonstrated a dose-related increase in cardiac output of up to 50% with a modest increase (5-10%) in heart rate. The majority of patients exhibited improvement in cardiac ejection fraction with minimal increase in cardiac work (as measured by the Pressure Rate Product). These positive hemodynamic effects were achieved without serious adverse events or adverse events leading to discontinuation of dosing. The drug was generally safe and well tolerated with good correlation between pharmacokinetic and pharmacodynamic parameters.

In November 2005, Neurocrine filed an IND application with the FDA to initiate a US Phase II study in stable CHF patients to further evaluate dose/response of urocortin 2 when administered over 4 hours. Results are anticipated in Q3 2006. This extended-infusion data will then provide guidance for dosing in the planned Phase IIb studies in the target population of patients with acute decompensated heart failure (ADHF). Results of this ADHF study are anticipated in the second half of 2007.

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 R_1 receptor antagonist compound is expected to complete Phase I in early 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 characteristics of escalating doses of this compound in healthy volunteers. Upon successful completion of Phase I studies, Phase II clinical trials are expected to begin in early 2006 including studies of the compound for treatment of depression/anxiety and IBS. In addition, a second, unique back-up compound is expected to enter Phase I clinical trials in the 1st Quarter of 2006.

Altered Peptide Ligand (APL) for Multiple Sclerosis (MS)
Results are expected in March 2006 from a Phase II nine-month clinical trial with NBI-5788 involving 157 patients for the treatment of relapsing MS. The study was designed to evaluate safety, tolerability and efficacy and it has been conducted at 28 sites in the US, Canada and Eastern Europe.

Altered Peptide Ligand (APL) for Type 1 Diabetes
Neurocrine has completed enrollment in a Phase II, dose-response, safety, tolerability and efficacy trial in approximately 188 adults/adolescents with new onset Type 1 Diabetes. Results from this study are expected in mid-2006.

Additional Compound for Insomnia To Enter Clinical Development
Neurocrine filed an IND in the first quarter of 2006 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. Phase I studies will evaluate the safety and PK of single and multiple doses as well as selected 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 year-end results and provide a Company update today, Monday, January 23rd at 4:30 PM Eastern Standard Time (EST) / 1:30 PM Pacific Standard Time (PST). The live Conference Call can be accessed by dialing 1-877-707-9628 (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 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 call concludes by dialing 1-800-839-5679 (US) or 402-220-2566 (International) and will be archived until Monday, February 6, 2006.

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, 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 associated with our reliance on our strategic partner for manufacturing and commercialization of indiplon; risk that following approval of indiplon, commercialization may be delayed for any of a number of reasons including market conditions and product supply; 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 FDA will not accept the IND filed by the Company for NBI-75043; risk that the GnRH receptor antagonist, urocortin 2, CRF and altered peptide ligand clinical candidates will not proceed to later stage clinical trials; risk that in later stage clinical trials the Company's clinical candidates will fail to demonstrate that they are safe and/or efficacious in treating the targeted disease states; 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2005	2004	2005	2004
	(unaudited)		(unaudited)	
Revenues:				
Sponsored research and development	$ 753	$ 10,676	$ 9,187	$ 27,156
License fees and milestones	5,358	7,809	92,702	57,612
Sales force allowance	8,000	—	22,000	—
Grant income	—	—	—	408
Total revenues	14,111	18,485	123,889	85,176
Operating expenses:				
Research and development	24,765	33,404	106,628	115,066
Sales, general and administrative	13,940	6,265	42,333	22,444
Total operating expenses	38,705	39,669	148,961	137,510
Loss from operations	(24,594)	(21,184)	(25,072)	(52,334)
Other income and (expenses):				
Interest income, net	626	783	2,858	6,775
Other income (expense), net	60	(214)	23	(214)
Total other income	686	569	2,881	6,561
Net loss	$ (23,908)	$ (20,615)	$ (22,191)	$ (45,773)
Net loss per common share:				
Basic and diluted	$ (0.65)	$ (0.57)	$ (0.60)	$ (1.26)
Shares used in the calculation of net loss per common share:				
Basic and diluted	36,992	36,477	36,763	36,201

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

	December 31, 2005 (unaudited)	December 31, 2004
Cash, cash equivalents and marketable securities	$ 273,068	$ 301,129
Other current assets	6,242	12,686
Total current assets	279,310	313,815
Property and equipment, net	99,307	102,166
Prepaid royalty	94,000	94,000
Other non-current assets	10,506	9,236
Total assets	$ 483,123	$ 519,217
Current liabilities	$ 33,693	$ 59,585
Long-term liabilities	59,326	65,805
Stockholders' equity	390,104	393,827
Total liabilities and stockholders' equity	$ 483,123	$ 519,217