



## Neurocrine Biosciences Reports Second Quarter 2006 Results

July 17, 2006

SAN DIEGO, July 17 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the quarter ended June 30, 2006. For the second quarter, the Company reported a net loss of \$27.4 million, or \$0.73 per share, compared with a net loss of \$5.6 million, or \$0.15 per share, for the same period last year. For the six months, the Company reported a net loss of \$53.4 million, or \$1.42 per share, as compared to \$24.4 million, or \$0.67 per share, for the same period last year. The adoption of Financial Accounting Standards Board Statement 123R "Share-Based Payment" (FAS 123R) resulted in non-cash operating expenses of approximately \$2.7 million and \$9.5 million for the three months and six months ended June 30, 2006, respectively.

"We continue to pursue activities to expedite successful registration and commercialization of indiplon and look forward to meeting with the FDA to finalize development plans for the resubmission of each indiplon NDA. At the same time, we look forward to reporting on the results of several other clinical development programs in 2006," said Gary A. Lyons, Neurocrine Biosciences President and Chief Executive Officer.

Revenues for the second quarter of 2006 were \$9.2 million, compared with \$33.2 million for the same period last year. Revenues for the six months ended June 30, 2006 were \$28.7 million, compared with \$45.0 million for the same period in 2005. The decrease in revenues for the three and six month periods is primarily due to lower revenue recognized under collaborative agreements. During the 2nd Quarter of 2006, Pfizer and Neurocrine announced the termination of this agreement as well as the global license agreement. During 2005, the Company recognized \$20.0 million in milestone payments related to indiplon development. Additionally, sponsored development revenue associated with the indiplon clinical program decreased compared to last year. The Company recognized \$263 thousand and \$6.1 million, respectively, for the three and six months ended June 30, 2006 in the form of sponsored development funding, compared to \$2.7 million and \$6.7 million for the three and six months ended June 30, 2005. License fees, milestones and sales force allowance recognized were \$9.0 million and \$21.6 million, respectively, for the three and six months ended June 30, 2006 and \$30.4 million and \$36.9 million for the three and six months ended June 30, 2005. Additionally, during the six-months ended June 2006 and 2005, the Company recognized a \$1.0 million milestone payment, in each period, related to advancements in the Corticotropin Releasing Factor (CRF) antagonist program from its collaboration with GlaxoSmithKline (GSK).

For the second quarter of 2006, research and development expenses decreased to \$26.1 million from \$29.6 million for the same period in 2005. For the six months ended June 30, 2006, research and development expenses were \$53.8 million, compared to \$55.2 million for the same period last year. This decrease in expenses reflects lower external development costs, primarily for indiplon, of \$5.4 million and \$7.9 million for the three and six months ended June 30, 2006, respectively. This decrease was offset by expenses related to the adoption of FAS 123R of \$1.9 million and \$3.9 million for the three and six months ended June 30, 2006.

Sales, general and administrative expenses increased to \$12.4 million for the second quarter of 2006, compared with \$9.8 million during the same period last year. For the six months ended June 30, 2006, sales, general and administrative expenses were \$31.7 million, compared to \$15.4 million for the first half of 2005. The increase in expenses from 2005 to 2006 primarily resulted from increased sales force related costs, of approximately \$3.1 million and \$10.1 million for the three and six months ended June 30, 2006, respectively. Additionally, the adoption of FAS 123R increased general and administrative expense by \$0.8 million and \$5.6 million for the three and six months ended June 30, 2006, respectively.

The Company's balance sheet on June 30, 2006 reflected total assets of \$442.5 million, including cash, cash equivalents, marketable securities, and receivables due under the collaboration agreement of \$234.7 million as compared with balances at December 31, 2005 of \$483.1 million and \$273.9 million, respectively.

### Financial Guidance for 2006

Based on recent events, Neurocrine is revising financial guidance for 2006. The Company expects the net cash burn for 2006 will be approximately \$100.0 million and expects to end 2006 with approximately \$180.0 million in cash and marketable securities. The net loss for 2006 will exceed \$130.0 million as a result of various non-cash charges such as FAS 123R charges. The Company is continuing to review its operating and financial resources to ensure that indiplon and other high priority development programs progress as quickly and efficiently as possible.

With respect to the sales force developed to market indiplon, the Company said it is exploring opportunities to bring in another product or products that would provide a near-term revenue stream to Neurocrine and enable the continued employment of this sales force before a launch of indiplon. It said that it cannot provide assurances that it can reach such an arrangement and if it does not, it will make decisions on the continued employment of the sales force so as to serve the best interests of the Company strategically and economically.

### Pipeline Update

Neurocrine is advancing six drug candidates through clinical development, in addition to indiplon capsules (IR) and tablets (MR), which will be the subject of discussions with the FDA. The Company is expecting to report on several Phase II and proof of concept clinical trials for its other compounds in the clinical pipeline throughout 2006 and 2007. At the same time, Neurocrine scientists will continue to build Neurocrine's pipeline and meet the Company-wide goal of bringing one new compound into clinical development each year.

### Indiplon for Insomnia

During the past several weeks the Company has been preparing to meet with the FDA to seek clarity and direction from the agency necessary for resubmission of New Drug Applications (NDAs) for indiplon capsules (IR) and tablets (MR). The first meeting for the IR formulation has been confirmed. The Company has requested a second meeting related to the MR formulation to follow the IR meeting. After both meetings have been completed, the Company will provide an update to its shareholders.

Neurocrine continues to present clinical data on indiplon IR and MR in peer-review forums. The Company and Clinical Investigators presented a total of 15 abstracts at the 2006 American Psychiatric Association (APA) and the Associated Professional Sleep Societies (APSS) Annual Meetings. Data presented included the results from clinical trials assessing the efficacy and safety of indiplon (capsules) IR and tablets (MR) in adults and elderly patients with insomnia. Among the data presented were the results from a 12-month study assessing the safety and tolerability of indiplon in primary insomnia, and results from a study on next day driving effects of indiplon.

#### Other Clinical Development Milestones Anticipated for 2006 and early 2007:

##### GnRH Antagonists for endometriosis:

- \* Completed results from a 3-month Phase II safety follow-up with GnRH antagonist (NBI-56418) for the treatment of endometrioses are expected in September 2006.
- \* Initiation of a 6-month Phase IIb clinical trial with NBI-56418 for the treatment of endometriosis is anticipated in late 3rd or early 4th Qtr 2006 and will involve 320 patients in 3 arms. The Company expects completion of the trial in late 2007 with results in early 2008; the primary endpoint of this trial is a clinically significant reduction in pain as measured by the Composite Pelvic Sign and Symptoms Score (CPSSS) and a key secondary endpoint is change in bone mineral density.
- \* Completion of a second Phase II 3-month clinical trial in endometriosis evaluating additional dose response is expected in the 4th Quarter of 2006.

##### Urocortin 2 for congestive heart failure:

- \* Results from a Phase II dose response trial involving patients with stable chronic heart failure (CHF) are expected in the 3rd Quarter of 2006. The purpose of the study is assessment of various hemodynamic endpoints including cardiac output as well as safety and PK/PD.
- \* Plans to initiate a Phase II trial in patients with acute decompensated heart failure are undergoing review.

##### CRF for IBS and Anxiety/Depression:

- \* GlaxoSmithKline is planning to initiate Phase II proof of concept clinical trials in 2006 using a CRF antagonist compound. These first Phase II trials will study the safety and efficacy of a CRF antagonist compound in patients with irritable bowel syndrome and in patients with anxiety.

##### APL Technology for Type-1 diabetes:

- \* Enrollment in a Phase II study of NBI-6024 in Type-1 diabetes has been completed in this Phase IIB proof of concept, dose-response, safety, tolerability and efficacy trial in approximately 188 adults/adolescents with new onset Type-1 diabetes.
- \* Results from a Phase II trial with APLs for Type 1 Diabetes are expected in September 2006

##### H1 Antagonists for insomnia:

- \* Completed a Phase I single dose study evaluating the safety and pharmacokinetics of an H1 antagonists for insomnia in healthy volunteers. Results are expected to be reported in the 2nd Half of 2006.
- \* Initiation of a Phase I multiple-dose trial in healthy volunteers to evaluate safety and PK is planned to begin in the 3rd Quarter of 2006.

#### Background Information on Neurocrine's Development Programs:

##### Three Phase II GnRH Studies for Endometriosis

Preliminary results from the first three month Phase II study of the Company's GnRH antagonist (NBI-56418) in 76 patients with endometriosis demonstrated that this orally active, small-molecule was safe, well-tolerated and was shown to provide a clinically significant reduction in pain as measured by the Composite Pelvic Sign and Symptoms Score (CPSSS), and other validated clinical measures for once daily NBI-56418. In addition, in contrast to injectable GnRH agonists, this oral antagonist was not associated with an increase in hot flashes while the VAS measurement of pain clearly showed pain reduction. Also, reduction in estrogen levels was correlated with efficacy. Results from the three-month safety follow-up period will be used to refine the larger six-month study.

Neurocrine is continuing to enroll patients in a second Phase II study in patients with endometriosis that was initiated in December 2005 with the objective of more fully exploring dose response. This study, a multi-dose, double-blind, placebo-controlled trial is enrolling 72 patients and is also

designed to assess safety and efficacy over a three-month period with the primary endpoint of reduction in endometriotic pain as measured by CPSSS. Enrollment is expected to be completed in August of 2006.

Neurocrine is planning to initiate a Phase IIb six-month treatment trial in patients with endometriosis to evaluate long-term efficacy and safety including possible changes in bone mineral density. In addition, the Company has completed a Phase I study in male volunteers as part of the Benign Prostate Hyperplasia development program, results of which will be announced during the 3rd Quarter.

#### Urocortin 2 for Congestive Heart Failure

Initial results of a Phase II study in patients with stable Congestive Heart Failure (CHF) indicate that urocortin 2 is generally well tolerated and that the predicted hemodynamic effects on systolic and diastolic blood pressure, heart rate, cardiac work and, most importantly, cardiac output occur over the entire 4-hour infusion. The study, a US Phase II study in stable CHF patients, was designed to further evaluate dose/response of urocortin 2 when administered over 4 hours.

#### Additional Compound for Insomnia in Clinical Development

Neurocrine initiated a Phase I study in the 1st Quarter of 2006 of a new orally active compound, NBI-75043, for the treatment of insomnia. The compound is a highly selective and short-acting H1 antagonist. The Phase I study evaluated the safety and pharmacokinetics (PK) of single and multiple doses as well as selected sleep-related parameters.

A second Phase I multiple-dose clinical trial is planned to further explore safety and PK as well as sleep related parameters.

Histamine, in addition to GABA-A, is a key regulator in the brain of sleep and wakefulness. A safe, likely non-scheduled, and effective H-1 antagonist would complement the use of other prescription sedative hypnotics.

#### Additional Research Programs

Neurocrine's Research Group 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 is also currently reviewing in preclinical studies a number of A2A lead antagonists for the treatment of Parkinson's disease.

#### Conference Call and Webcast Today at 5:00 PM EDT/2:00 PM PDT

Neurocrine will also host a live conference call and Webcast to discuss its second quarter financial results and provide a Company update Monday, July 17th, 2006 at 5:00 p.m. Eastern Daylight Time (EDT) / 2:00 pm Pacific Daylight Time (PDT). Participants can access the live conference call by dialing 800-540-0559 (US) or 785-832-0326 (International) 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 conclusion of the call by dialing 877-710-5301 (US) or 402-220-1604 (International). The call will be archived until Monday, July 31, 2006.

Neurocrine Biosciences, Inc. is a 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, irritable bowel syndrome, and CNS related disorders. 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 in general, as well as risks and uncertainties associated with the Company's indiplon program and clinical pipeline. Specifically, the risks and uncertainties associated with the Company's indiplon program include but not limited to the risk that the Company will not be able to address issues and or requests set forth in the action letters from the FDA in a timely manner; risk that the FDA may reject any further indiplon regulatory filings or find them incomplete or insufficient; risk that indiplon approval and subsequent commercialization may be significantly delayed, and risk that indiplon will never be approved by the FDA or commercialized. In addition, the Company faces risks and uncertainties with respect to the Company's clinical pipeline including risk that the Company's GnRH receptor antagonist, urocortin 2, CRF antagonist, altered peptide ligand and H1 antagonist clinical candidates will not proceed to later stage clinical trials; risk relating to the Company's dependence on contract manufacturers for clinical drug supply; 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, 2005 and the Company's report on Form 10-Q for the quarter ended March 31, 2006. 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		Six Months Ended	
June 30,		June 30,	
2006	2005	2006	2005
(unaudited)		(unaudited)	

Revenues:				
Sponsored research and development	\$277	\$2,721	\$6,155	\$7,137
License fees and milestones	727	25,448	6,085	31,896
Sales force allowance	8,240	5,000	16,480	6,000
Total revenues	9,244	33,169	28,720	45,033
Operating expenses:				
Research and development	26,112	29,633	53,847	55,236
Sales, general and administrative	12,396	9,788	31,731	15,396
Total operating expenses	38,508	39,421	85,578	70,632
Loss from operations	(29,264)	(6,252)	(56,858)	(25,599)
Other income and (expenses):				
Interest income and expense, net	1,815	659	3,508	1,176
Other income and (expense), net	--	(11)	--	(11)
Total other income	1,815	648	3,508	1,165
Net loss	\$(27,449)	\$(5,604)	\$(53,350)	\$(24,434)
Net loss per common share:				
Basic and diluted	\$(0.73)	\$(0.15)	\$(1.42)	\$(0.67)
Shares used in the calculation of net loss per common share:				
Basic and diluted	37,764	36,647	37,560	36,623

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

	June 30, 2006	December 31, 2005
	(unaudited)	
Cash, cash equivalents and marketable securities	\$234,319	\$273,068
Other current assets	6,308	6,242
Total current assets	240,627	279,310
Property and equipment, net	96,693	99,307
Prepaid royalty	94,000	94,000
Other non-current assets	11,223	10,506
Total assets	\$442,543	\$483,123
Current liabilities	\$23,932	\$33,693
Long-term liabilities	56,839	59,326
Stockholders' equity	361,772	390,104
Total liabilities and stockholders' equity	\$442,543	\$483,123

SOURCE Neurocrine Biosciences, Inc.

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