



Neurocrine Biosciences Reports Third Quarter 2006 Results

November 2, 2006

Company Also Provides Update on Indiplon Program

SAN DIEGO, Nov 02, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that based on guidance from the U.S. Food and Drug Administration (FDA) at the end-of-review meetings for indiplon capsules and indiplon tablets New Drug Applications (NDAs), and related communications from these meetings, the Company is finalizing a path forward for the indiplon program.

The Company's discussions with the FDA on the indiplon capsules NDA have been focused on the actions necessary to bring indiplon capsules from Approvable to Approval for the treatment of insomnia. The FDA requested that the resubmission include further analyses and modifications of analyses previously submitted to address questions raised by the Agency in the initial review. The reanalysis is ongoing. The FDA also requested and the Company has completed a supplemental pharmacokinetic/food effect profile of indiplon capsules including several meal types. While the FDA has not requested any additional clinical studies for the indiplon capsules resubmission, the Company has elected to conduct an additional 3-month safety and efficacy study to supplement the reanalysis and provide additional support for the resubmission. The NDA for indiplon capsules is targeted to be resubmitted to the FDA during summer 2008.

The Company's discussions with the FDA on the indiplon tablets NDA have been focused on the actions necessary to bring indiplon tablets from Non-Approvable to Approval for the treatment of insomnia. The FDA Non-Approvable Letter requested that the Company reanalyze certain safety and efficacy data. The FDA has requested additional long-term safety and efficacy data with the 15 mg dose for the adult population and the development of a separate dose for the elderly population. In their discussions, the Company and the FDA noted positive efficacy data for sleep maintenance with both indiplon capsules and tablets. On the basis of these discussions, the Company is formulating a strategy to pursue a sleep maintenance claim for indiplon. The evaluation of indiplon for sleep maintenance will include both indiplon capsules and tablets.

"Now that we have received clarification from the FDA on the requirements for indiplon, we believe that indiplon will be best served by focusing our resources on the resubmission of the NDA to secure approval for indiplon capsules. While the Agency did not request additional studies for indiplon capsules, we have decided to take the most conservative approach and conduct an additional 3-month safety and efficacy study for sleep onset to ensure the highest probability for the success of the resubmission. We will be pursuing a sleep maintenance claim for indiplon to be filed as a separate application at a later date," said Gary A. Lyons, President and CEO of Neurocrine Biosciences.

The Company Also Announced Financial Results

In addition, the Company today announced its financial results for the quarter ended September 30, 2006. For the third quarter of 2006, the Company reported a net loss of \$39.1 million, or \$1.03 loss per share compared to net income of \$26.2 million, or \$0.71 basic earnings per share, for the same period in 2005. For the nine months ended September 30, 2006, the Company reported a net loss of \$92.5 million, or \$2.46 loss per share compared to net income of \$1.7 million, or \$0.05 basic earnings 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 \$3.2 million and \$12.7 million for the three months and nine months ended September 30, 2006, respectively. Additionally, the Company incurred a one-time cost of approximately \$9.5 million related to severance and outplacement costs during the third quarter of 2006. During the three and nine months ended September 30, 2005, the Company recognized milestones of \$50.0 and \$71.0 million under collaboration agreements.

Revenues for the third quarter of 2006 were \$1.1 million compared with \$64.7 million for the respective period last year. Revenues for the nine months ended September 30, 2006 were \$29.8 million compared with \$109.8 million for the same period in 2005. The decrease in revenues for the three and nine month periods is primarily due to achievement of a \$50.0 million milestone under the Pfizer collaboration agreement in the third quarter of 2005. The Company recognized \$0.3 million and \$6.5 million, for the three and nine months ended September 30, 2006 in the form of sponsored development funding under the Pfizer collaboration agreement compared to \$1.3 million and \$7.9 million for the three and nine months ended September 30, 2005. License fees and milestones recognized under the Pfizer collaboration were \$0.7 million and \$5.8 million for the three and nine months ended September 30, 2006 and \$55.4 million and \$86.3 million for the three and nine months ended September 30, 2005. The sales force allowance earned under the Pfizer collaboration agreement was \$16.5 million and \$14.0 million for the nine months ended September 30, 2006 and 2005, respectively, and \$8.0 million for the third quarter of 2005.

Research and development expenses decreased to \$25.2 million for the third quarter of 2006 from \$26.6 million for the respective period in 2005. For the nine months ended September 30, 2006 and 2005, research and development expenses were \$79.1 million and \$81.9 million, respectively. This decrease in research and development expenses primarily resulted from lower external development costs offset by severance payments totaling \$2.8 million.

Sales, general and administrative expenses increased to \$16.1 million for the third quarter of 2006 compared with \$13.0 million during the same period last year. For the nine months ended September 30, 2006, sales, general and administrative expenses were \$47.8 million compared to \$28.4 million for the respective period in 2005. This increase in sales, general and administrative expenses during the third quarter primarily resulted from severance payments totaling \$6.7 million offset by lower operating costs. The year to date increase in sales, general and administrative expenses was the result of higher aggregate head count in 2006 as compared to 2005 and the adoption of FAS 123R.

The Company's balance sheet on September 30, 2006 reflected total assets of \$404.1 million, including cash, cash equivalents, marketable securities, and receivables due under collaboration agreements of \$200.2 million as compared with balances at December 31, 2005 of \$483.1 million and \$273.9 million, respectively.

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, cash equivalents and marketable securities. The net cash burn for 2007 is expected to be approximately \$80.0 million.

"As part of our business strategy we have always maintained a strong and diversified R & D pipeline and are encouraged by the progress of the next generation of products that have advanced through development this past quarter, especially our GnRH and CRF programs. Our R & D group continues to build up the pipeline and we are proud to announce the selection of a new development candidate, sNRI for neuropathic pain, which is expected to enter Phase I clinical trials by year-end," said Gary A. Lyons, President and CEO of Neurocrine Biosciences.

"Over the last few months we have implemented a number of important organizational changes at the Company. We are proud of the promotions of Kevin Gorman Ph.D to Chief Operating Officer and Tim Coughlin to Chief Financial Officer and appreciate the strengths and expertise they bring to our senior management team as we move the pipeline forward," added Lyons.

"As part of our financial strategy, we have reallocated resources and adjusted operating expenses in order to meet the funding requirements for continued development of our pipeline. We plan to continue to maintain a well- controlled burn rate and will also review collaborative alternatives and outside funding strategies to achieve these goals," said Timothy P. Coughlin, Vice President and Chief Financial Officer of Neurocrine Biosciences.

Pipeline Update

Neurocrine is advancing six drug candidates through clinical development. The Company is expecting to report on several Phase II clinical trials in the fourth quarter of 2006 and throughout 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 development each year.

GnRH Antagonists for endometriosis:

- * Initiated a 6-month Phase IIb clinical trial with NBI-56418 for the treatment of endometriosis during the 4th Quarter 2006.
- * Preliminary top line results from a second Phase II 3-month clinical trial in endometriosis evaluating additional dose response expected in the 4th Quarter of 2006.

Urocortin 2 for CHF:

- * Results from a Phase II dose response trial involving patients with stable congestive heart failure (CHF) expected in the 4th Quarter 2006.

CRF Antagonists for IBS and Anxiety/Depression:

- * Neurocrine expects the first exploratory studies in patients with irritable bowel syndrome (IBS) to start during the 4th Quarter of 2006.
- * Neurocrine expects Phase II "proof of concept" trials in two indications, IBS and anxiety, to be initiated late in 2006.
- * A back up compound is currently in Phase I multi-dose trials.

Selective Norepinephrine Reuptake Inhibitor (sNRI) for Neuropathic Pain

- * New clinical candidate for neuropathic pain expected to enter Phase I clinical trials in late 4th Quarter 2006 or early 1st Quarter 2007.

GnRH Antagonists:

Neurocrine recently received communication from the FDA securing agreement to a non-clinical registration plan and the Phase IIb 6 month clinical trial design. The Company previously reported positive safety and efficacy results with completion of the 3-month off-treatment period of its 6-month 'proof of concept', safety, efficacy and dose-finding Phase II clinical trial using its proprietary, orally-active, non-peptide Gonadotropin-Releasing Hormone (GnRH) receptor antagonist (NBI-56418). The Company had previously reported positive preliminary results from the completion of the first 3-month double-blind treatment period of this Phase II trial in April 2006.

Based on these data, Neurocrine plans to move ahead with an expanded six-month study in patients with endometriosis. This Phase IIb study will include several hundred patients and has been initiated during the 4th Quarter of 2006. In addition to confirming the effect of NBI-56418 on endometriotic pain, this study is designed primarily to assess the impact of longer treatment on bone mineral density as measured by DEXA scan. The Company expects completion of the trial in mid-2008.

Neurocrine also completed enrollment of patients in a second Phase II study in patients with endometriosis to explore once vs. twice daily dosing. This study, a multi-dose, double-blind, placebo-controlled trial, enrolled 68 patients and is designed to assess safety and efficacy over a 3-month period of active treatment followed by an additional 3 months off treatment. The primary endpoint of reduction in endometriotic pain will be measured by the Composite Pelvic Sign and Symptoms Score (CPSSS) and the Visual Analog Scale (VAS). Preliminary top line results are expected to be announced toward the end of the 4th Quarter of 2006.

Urocortin 2 for CHF

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 assess various hemodynamic endpoints, safety and PK/PD over the 4-hour infusion treatment period. Results are expected in the 4th Quarter of 2006.

CRF for Anxiety/Depression and IBS

The CRF collaboration between Neurocrine and GlaxoSmithKline (GSK) has identified multiple unique high affinity and selective antagonists for the CRF receptor that are currently in clinical development for depression and anxiety-related disorders and Irritable Bowel Syndrome (IBS). Neurocrine expects the first exploratory studies in patients with IBS to be initiated during the 4th Quarter of 2006. Neurocrine expects two additional Phase II "proof of concept" trials to be initiated in the 4th Quarter of 2006, one in patients with IBS and a second trial in patients with anxiety. GSK has also advanced a back up CRF receptor antagonist into a Phase I single dose study in the 1st Quarter of 2006 and this compound is now in a Phase I multi-dose study.

New Drug Candidate Selected for Clinical Development Pipeline

Neurocrine has selected a new compound, a selective norepinephrine reuptake inhibitor (SNRI) for development for treatment of neuropathic pain and psychiatric disorders. Based on its selective pharmacologic effect as a norepinephrine re-uptake inhibitor, this drug also has potential clinical utility in a variety of other therapeutic areas including psychiatry, gastroenterology and urology. Phase I clinical trials are expected to be initiated in late 2006 or early 2007.

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 antagonists for the treatment of Parkinson's disease.

Conference Call and Webcast Today at 5:00 PM Eastern Standard Time

Neurocrine will host a live conference call and Webcast to discuss its third quarter financial results and provide a Company update November 2, 2006 at 5:00 p.m. Eastern Standard Time (EST) / 2:00 p.m. Pacific Standard Time (PST). Participants can access the live conference call by dialing 1-800-903-0258 (US) or 1-785-832-0326 (International) using the conference ID# 7NBIX. 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 1-800-695-0974 (US) or 1-402-220-1459 (International). The call will be archived for two weeks.

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, 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 are not limited to the risk that the Company's reanalysis of the indiplon capsule clinical data requested by the FDA will not demonstrate the safety and/or efficacy of indiplon capsules; risk that the additional indiplon clinical trials the Company plans to conduct to support its regulatory filings will fail to demonstrate that indiplon is safe and/or efficacious; 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 relating to the availability of resources to conduct the additional indiplon clinical trials and prepare and resubmit the indiplon regulatory filings; risk that the FDA may reject any further indiplon regulatory filings or find them incomplete or insufficient; risk that the FDA may determine that the Company's indiplon clinical data will not support the indiplon labeling sought by the Company; risk that indiplon approval and subsequent commercialization may be significantly delayed; risk that we may be not be successful in finding another indiplon collaboration partner on favorable terms or at all and that failure to obtain a new partner could adversely effect indiplon development and commercialization; 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 indiplon program and clinical pipeline including risk that the Company's GnRH receptor antagonist, urocortin 2, CRF antagonist, and SNRI 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 June 30, 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 per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2006	2005	2006	2005
	(unaudited)		(unaudited)	
Revenues:				
Sponsored research and development	\$348	\$1,297	\$6,503	\$8,434
License fees and milestones	726	55,448	6,811	87,344

Sales force allowance	--	8,000	16,480	14,000
Total revenues	1,074	64,745	29,794	109,778
Operating expenses:				
Research and development	25,223	26,627	79,070	81,863
Sales, general and administrative	16,047	12,997	47,778	28,393
Total operating expenses	41,270	39,624	126,848	110,256
Income (loss) from operations	(40,196)	25,121	(97,054)	(478)
Other income and (expenses):				
Interest income and expense, net	1,525	1,056	5,033	2,232
Other income and (expense), net	(472)	(26)	(472)	(37)
Total other income	1,053	1,030	4,561	2,195
Net income (loss)	\$(39,143)	\$26,151	\$(92,493)	\$1,717
Net income (loss) per common share:				
Basic	\$(1.03)	\$0.71	\$(2.46)	\$0.05
Diluted	\$(1.03)	\$0.68	\$(2.46)	\$0.05
Shares used in the calculation of net income (loss) per common share:				
Basic	37,868	36,707	37,664	36,685
Diluted	37,868	38,406	37,664	37,992

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

	September 30, 2006 (unaudited)	December 31, 2005
Cash, cash equivalents and marketable securities	\$199,778	\$273,068
Other current assets	5,002	6,242
Total current assets	204,780	279,310
Property and equipment, net	93,868	99,307
Prepaid royalty	94,000	94,000
Other non-current assets	11,483	10,506
Total assets	\$404,131	\$483,123
Current liabilities	\$21,267	\$33,693
Long-term liabilities	56,388	59,326
Stockholders' equity	326,476	390,104
Total liabilities and stockholders' equity	\$404,131	\$483,123

SOURCE Neurocrine Biosciences, Inc.

Elizabeth Foster or Claudia Woodworth, both of Neurocrine Biosciences,
+1-858-617-7600

<http://www.neurocrine.com>