Neurocrine Biosciences Reports Third Quarter 2010 Results

October 28, 2010

SAN DIEGO, Oct 28, 2010 /PRNewswire via COMTEX/ --

Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the quarter ended September 30, 2010.

For the third quarter of 2010, the Company reported net income of $3.3 million, or $0.06 per share, compared with a net loss of $8.2 million, or $0.21 per share, for the same period in 2009. For the nine months ended September 30, 2010, the Company reported a net loss of $10.5 million, or $0.20 per share, as compared to a net loss of $43.1 million, or $1.11 per share, for the same period last year.

The Company's balance sheet on September 30, 2010 reflected total assets of $149.9 million, including cash, investments and receivables of $140.4 million.

"The financial impact of our two recent collaboration agreements with Abbott and Boehringer Ingelheim is evident in these third quarter financial results and the cash and investments position of Neurocrine," said Timothy P. Coughlin, Chief Financial Officer of Neurocrine Biosciences. "We will continue the fiscal discipline that has been ingrained in the Company over the past three years, while advancing our lead clinical programs; elagolix, VMAT2 and Urocortin 2 and bringing new clinical candidates forward from our research and discovery platform."

Revenues for the third quarter of 2010 were $14.4 million, compared to $0.7 million for the same period in 2009. Revenues for the nine months ended September 30, 2010 were $19.8 million, compared with $2.2 million for the same period in 2009. The increase in revenue is due to our recently executed collaboration agreements with Abbott and Boehringer Ingelheim, for our GnRH (elagolix) and GPR119 programs, respectively. During the third quarter of 2010, we recognized revenue of $8.5 million from amortization of up-front license fees and $5.2 million resulting from internal and external research and development expense reimbursement under these two agreements. During the nine month period ending September 30, 2010, we recognized revenue of $11.1 million from amortization of up-front license fees and $6.5 million resulting from internal and external research and development expense reimbursement under these two agreements.

Research and development expenses increased to $8.2 million during the third quarter of 2010 compared with $7.4 million for the same period in 2009, primarily due to a one time personnel bonus during the third quarter of 2010.For the nine months ended September 30, 2010, research and development expenses were $23.1 million, compared to $29.1 million for the same period last year. The decrease in year-to-date research and development expenses is primarily due to a restructuring program enacted in the second quarter of 2009 coupled with ongoing expense management efforts.

General and administrative expenses increased to $3.6 million during the third quarter of 2010 compared with $3.0 million for the same period last year, primarily due to a one time personnel bonus during the third quarter of 2010. For the nine months ended September 30, 2010, general and administrative expenses were $10.0 million, compared to $12.0 million for the first half of 2009. The decrease in general and administrative expenses is primarily due to a restructuring program enacted in the second quarter of 2009 coupled with ongoing expense management efforts.

Other income decreased to $0.9 million during the third quarter of 2010 from $1.5 million of other income for the third quarter of 2009. Other income increased from $1.6 million of income during the first nine months of 2009 to $3.1 million of other income for the first nine months of 2010. This change resulted primarily from a one-time $1.5 million loss recognized on auction rate securities in the first quarter of 2009.

Pipeline Highlights

Elagolix Update

Neurocrine and Abbott filed the end of Phase II meeting request with the FDA in late September 2010, an end of Phase II meeting is scheduled to occur in January 2011. Upon receipt of the written minutes of the meeting, the Company will provide an update as to the timing around the elagolix program.

Technology and information transfer from Neurocrine to Abbott are underway and proceeding well. The transfer of the Investigational New Drug applications for elagolix from Neurocrine to Abbott has been completed. Abbott and Neurocrine are currently planning Endometriosis Phase III and Uterine Fibroids Phase II studies.

The four month open label extension portion of the Daisy PETAL Study (901) was completed in late September 2010. We expect to have additional safety and efficacy data from this portion of the 901 study later this year.

Urocortin 2 Update

The Christchurch Cardioendocrine Research Group at University of Otago, Christchurch School of Medicine and Health Sciences, New Zealand, in collaboration with the Company, is enrolling patients with Acute Decompensated Heart Failure in a Phase II study of Urocortin 2, and has enrolled 32 patients as of mid October, of a planned total patient population of 50.

Additionally, Urocortin 2 studies are underway at the Centre for Cardiovascular Sciences at The University of Edinburgh through a British Heart Foundation grant. The first component of nine studies are being conducted in both healthy volunteers and patients with stable congestive heart failure to determine the impact of Urocortin 2 infusions on biomarkers of cardiovascular function and dysfunction.

VMAT2 Update

The VMAT2 development program successfully completed Phase I safety studies in healthy male volunteers. Neurocrine plans to initiate a Phase IIa dose exploration study in patients with Tardive Dyskinesia in late 2010.

Corticotropin Releasing Factor (CRF1) Receptor Antagonists Update

GSK completed a multicenter randomized, double-blind, placebo-controlled trial designed to assess the safety and efficacy of GSK561679 in approximately 150 subjects with Major Depressive Disorder over six weeks of treatment. Statistical analysis using the intent-to-treat population revealed no benefit of GSK561679 compared with placeboon both the Bech Melancholia and HAMD-17 endpoints.

Emory University of Atlanta and Mt. Sinai Medical Center in New York, in conjunction with GSK, have recently initiated a Phase II clinical trial evaluating GSK561679 in women with post-traumatic stress disorder. This study is a randomized, double-blind, placebo-controlled trial which is expected to enroll approximately 150 patients for a six-week treatment period and is expected to take several years to complete.

Conference Call and Webcast Friday, October 29, 2010 at 8:30 a.m. ET

Neurocrine will hold a live conference call and webcast tomorrow morning, Friday, October 29, 2010 at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time). Participants can access the live conference call by dialing 1-800-894-5910 (US) or 785-424-1052 (International) using the conference passcode 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 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 1-800-695-1564 (US) or 402-530-9025 (International) using the passcode 7NBIX. 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 endometriosis, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia, and other neurological and endocrine related diseases and 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 R & D pipeline and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's R & D pipeline include risk that elagolix, the company's lead clinical program, will fail to demonstrate that elagolix is safe and effective; risk that elagolix will not proceed to Phase III clinical trials; and risks associated with the Company's dependence on corporate collaborators for Phase III development, commercial manufacturing and marketing and sales activities. In addition, the Company faces risks and uncertainties with respect to the rest of the Company's R & D pipeline including risk that the Company's clinical candidates will not be found to be safe and effective; risk that the Company's urocortin 2, VMAT2 and CRF clinical candidates will not proceed to later stage clinical trials; risk that the GPR119 program will not provide any pre-clinical candidates for further development and risk that the Company's research programs will not identify pre-clinical candidates for further development. With respect to its pipeline overall, the Company faces risk that it will be unable to raise additional funding required to complete development of all of its product candidates; 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; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2009 and Form 10-Q for the quarter ended June 30, 2010. 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 loss per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(unaudited)		(unaudited)	
Revenues:				
Sponsored research and development	$ 5,210	$ 3	$ 6,519	$ 23
License fees and milestones	9,238	730	13,325	2,190
Total revenues	14,448	733	19,844	2,213
Operating expenses:				
Research and development	8,227	7,401	23,086	29,057
General and administrative	3,635	2,966	9,950	11,988
Cease use expense	120	89	401	5,858
Total operating expenses	11,982	10,456	33,437	46,903
Income (loss) from operations	2,466	(9,723)	(13,593)	(44,690)
Other income and (expense):				
Interest income and other income (expense)	118	281	791	(1,249)
Gain on disposal of assets	749	1,265	2,347	2,817
Total other income (expense) net	867	1,546	3,138	1,568

Net income (loss)	$ 3,333	$ (8,177)	$ (10,455)	$ (43,122)
Net income (loss) per common share:				
Basic and diluted	$ 0.06	$ (0.21)	$ (0.20)	$ (1.11)
Shares used in the calculation of net loss per common share:				
Basic	54,844	39,096	52,130	38,938
Diluted	55,648	39,096	52,130	38,938

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2010 (unaudited)	December 31, 2009
Current assets:		
Cash and investments	$ 124,971	$ 53,464
Accounts receivable	5,219	-
Other current assets	1,402	1,923
Total current assets	131,592	55,387
Property and equipment, net	1,827	2,695
Long-term investments	10,181	6,411
Restricted cash	6,333	6,325
Total assets	$ 149,933	$ 70,818
Current liabilities	$ 53,184	$ 19,961
Long-term liabilities	80,102	46,903
Stockholders' equity	16,647	3,954
Total liabilities and stockholders' equity	$ 149,933	$ 70,818

SOURCE Neurocrine Biosciences, Inc.