Neurocrine Biosciences Reports Fourth Quarter and Year End 2011 Results

February 8, 2012

SAN DIEGO, Feb. 8, 2012 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its financial results for the quarter and year ended December 31, 2011.

For the fourth quarter of 2011, the Company reported net income of $1.3 million, or $0.02 per fully diluted share, compared to net income of $2.5 million, or $0.04 per fully diluted share, for the same period in 2010.

For the year ended December 31, 2011, the Company reported net income of $37.6 million, or $0.67 per fully diluted share, as compared to a net loss of $8.0 million, or $0.15 per basic share, for 2010. One-time milestone payments of $30.0 million during 2011 accounted for the improvement in operating results year over year.

The Company's balance sheet at December 31, 2011 reflected total assets of $138.4 million, including cash, investments and receivables of $131.7 million compared with balances at December 31, 2010 of $144.4 million and $135.9 million, respectively. During January 2012, the Company completed a public offering of approximately 10.9 million shares of common stock that resulted in net proceeds of approximately $82.8 million.

"During 2011, we maintained our financial discipline and performed to plan," said Kevin C. Gorman, President and CEO of Neurocrine Biosciences. "From a scientific perspective we completed our first open-label Phase II study of our VMAT2 inhibitor, NBI-98854. We also opened the related IND for NBI-98854 in the United States, and recently completed enrollment in our placebo controlled double-blind Phase II study of VMAT2 which will read out later this quarter. Elagolix continued to move forward with our partner Abbott, starting a Phase II study in uterine fibroids, and more recently filing for an SPA with the FDA for endometriosis. Additionally, we have several novel compounds that were discovered by our research group during 2011 that we will continue to work on in 2012, with the goal of beginning the IND process on at least one of these novel compounds by year end."

Revenues for the fourth quarter of 2011 were $11.1 million, compared to $13.7 million for the same period in 2010. The $2.6 million decrease in revenue is primarily due to lower reimbursed expenses under the Company's collaboration agreement with Abbott. Revenues for the year ended December 31, 2011 were $77.4 million, compared with $33.5 million for 2010. The $43.9 million increase in revenue is primarily due to $30 million in milestones achieved under the Company's collaboration agreement with Abbott during the third quarter of 2011. The increase in year-to-date revenue is also a result of a full year of revenue recognition under the collaboration agreements with Abbott and Boehringer Ingelheim, for our GnRH and GPR119 programs, respectively. The Company entered into both of these collaboration agreements in June of 2010.

Research and development expenses decreased to $8.0 million during the fourth quarter of 2011 compared with $8.1 million for the same period in 2010. For the year ended December 31, 2011, research and development expenses were $31.0 million, compared to $31.2 million for 2010. Although research and development expenses are relatively flat year over year, external research and development expenses have shifted from the elagolix program, which Abbott is now responsible for, to the Company's VMAT2 inhibitor program.

General and administrative expenses decreased to $2.7 million during the fourth quarter of 2011 compared with $3.3 million for the same period last year, primarily due to decreased personnel related costs and decreased facility related costs. For the year ended December 31, 2011, general and administrative expenses were $12.5 million, compared to $13.3 million for 2010. The decrease in year-to-date general and administrative expenses is primarily due to lower facility related costs and lower ongoing personnel related costs.

Other income decreased to $0.9 million during the fourth quarter of 2011 from $2.6 million of other income for the fourth quarter of 2010. Other income decreased to $3.6 million during the year ended December 31, 2011 from $5.8 million of other income for the year ended December 31, 2010. These changes resulted primarily from $0.7 million of one-time gains recognized related to the sale of auction rate securities during the fourth quarter of 2010 and $1.0 million received in 2010 related to four research and discovery programs that received funding under the 2010 Qualifying Therapeutic Discovery Project Program enacted as part of the health care reform legislation.

2012 Financial Guidance

The Company expects to have a net cash burn from operations of approximately $40 to $45 million in 2012. Revenue is expected to approximate $40 to $45 million which includes amortization of up-front license fees of approximately $34 million. Expenses for 2012 should approximate $55 to $60 million. Net loss for 2012 is expected to be $9 to $14 million, or $0.14 to $0.21 loss per share based on 66 million basic shares outstanding. The Company expects to end 2012 with approximately $170 million in cash, investments and receivables.

Pipeline Highlights

Elagolix Update

Abbott and Neurocrine held several Type C meetings with the FDA during 2011 for the endometriosis indication. This series of meetings has resulted in Abbott submitting a Special Protocol Assessment (SPA) with the FDA on the design of the Phase III program for elagolix. The Phase III clinical program of elagolix for endometriosis is expected to commence in the first half of 2012.

Abbott is also currently enrolling subjects in a large Phase II study of elagolix in uterine fibroids subjects.

VMAT2 Update

The Company's VMAT2 inhibitor, NBI-98854, successfully completed two Phase I safety studies in healthy male volunteers and a Phase IIa study in tardive dyskinesia patients. Based on these three Canadian studies, the Company filed an Investigational New Drug Application (IND) with the FDA Division of Psychiatry Products.

Following the IND application with the FDA, a second Phase II study was initiated in the United States to further assess NBI-98854 in tardive dyskinesia patients. The design of this second Phase II study is a randomized, double-blind, placebo controlled, cross-over trial, using a within-subject comparison for safety and efficacy evaluation. This 32-patient study is assessing once-daily NBI-98854 (12.5mg or 50mg) over a two-week dosing period. The primary endpoint of the study will be a comparison of placebo vs. active scores on the Abnormal Involuntary Movement Scale (AIMS). The study has completed enrollment and the Company expects the results of this study in March 2012.

The Company has also conducted a successful three-month in-vivo toxicology study to support longer dosing regimens. This, along with the second Phase II study, will be used to inform a larger Phase IIb program that is planned to be initiated during 2012 to assess three-month dosing of NBI-98854.

In January of 2012, the Company was notified that the FDA had granted Fast Track status to NBI-98854 for neuroleptic-induced tardive dyskinesia. The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs intended to treat serious diseases and address unmet medical needs.

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 conducting a Phase II study of urocortin 2 in Acute Decompensated Heart Failure patients. This study has now completed enrollment and top-line results are expected later in the first quarter of 2012.

Additionally, urocortin 2 studies are underway at the Centre for Cardiovascular Sciences at The University of Edinburgh through a British Heart Foundation grant. Nine studies are expected to be 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.

The Company has completed several Phase I studies and two Phase II studies of urocortin 2 in patients with stable congestive heart failure. These Phase II studies showed urocortin 2 to be well tolerated with positive hemodynamic effects as evidenced by increases in cardiac output and efficiency.

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

Neurocrine will hold a live conference call and webcast today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). Participants can access the live conference call by dialing 800-894-5910 (US) or 785-424-1052 (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 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 800-688-9445 (US) or 402-220-1371 (International) using the conference ID: NBIX. The call will be archived for two weeks.

Neurocrine Biosciences, Inc. is a biopharmaceutical company focused on neurological and endocrine-related diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, stress-related disorders, pain, tardive dykinesia, uterine fibroids, diabetes, 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 and VMAT2 clinical candidates will not proceed to later stage clinical trials; 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, 2010 and Form 10-Q for the quarter ended September 30, 2011. 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 per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2011	2010	2011	2010
Revenues:				
Sponsored research and development	$ 1,873	$ 4,419	$ 10,462	$ 10,938
Milestones and license fees	9,237	9,238	66,951	22,563
Total revenues	11,110	13,657	77,413	33,501
Operating expenses:				

Research and development	8,002	8,065	30,951	31,151
General and administrative	2,668	3,323	12,458	13,273
Cease-use expense	(7)	2,398	82	2,799
Total operating expenses	10,663	13,786	43,491	47,223
Income (loss) from operations	447	(129)	33,922	(13,722)
Other income:				
Gain on sale/disposal of assets	58	92	242	294
Deferred gain on real estate	744	722	2,953	2,867
Investment income, net	77	806	418	1,538
Other income, net	5	996	36	1,055
Total other income	884	2,616	3,649	5,754
Net income (loss)	$ 1,331	$ 2,487	$ 37,571	$ (7,968)
Net income (loss) per common share:				
Basic	$ 0.02	$ 0.05	$ 0.68	$ (0.15)
Diluted	$ 0.02	$ 0.04	$ 0.67	$ (0.15)
Shares used in the calculation of net income (loss) per common share:				
Basic	55,259	54,869	55,176	52,820
Diluted	56,461	56,245	56,347	52,820

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

	December 31, 2011	December 31, 2010
Cash, cash equivalents and short-term marketable securities	$ 129,103	$ 126,865
Other current assets	3,373	6,186
Total current assets	132,476	133,051
Property and equipment, net	1,586	1,532
Long-term investments	—	3,739
Restricted cash	4,306	6,102
Total assets	$ 138,368	$ 144,424
Current liabilities	$ 47,110	$ 52,777
Long-term liabilities	31,177	72,302
Stockholders' equity	60,081	19,345
Total liabilities and stockholders' equity	$ 138,368	$ 144,424

SOURCE Neurocrine Biosciences, Inc.

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