Neurocrine Biosciences Reports Second Quarter 2012 Results

July 31, 2012

ELAGOLIX ENTERS PHASE III, VMAT2 PHASE IIB STUDY STARTS IN THIRD QUARTER

SAN DIEGO, July 31, 2012 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended June 30, 2012. For the second quarter of 2012, the Company reported a net loss of $0.5 million, or $0.01 loss per share, compared to net income of $2.0 million, or $0.04 per share, for the same period in 2011. For the six months ended June 30, 2012, the Company reported a net loss of $1.4 million, or $0.02 loss per share, as compared to net income of $4.9 million, or $0.09 per share, for the first half of last year.

The Company's balance sheet at June 30, 2012 reflected cash, cash equivalents, investments and receivables under collaboration agreements of $194.7 million compared to $203.2 million at March 31, 2012.

"The elagolix program achieved a significant milestone this past quarter with the start of Phase III studies in endometriosis," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "This coupled with the continued progress of elagolix in the Phase II uterine fibroids study, preparations for the VMAT2 Phase IIb program which is on track to start in August, and advancements in early research programs served for a very productive quarter."

Revenues for the second quarter of 2012 were $10.6 million, compared to $12.2 million for the same period in 2011. Revenues for the six months ended June 30, 2012 were $21.8 million, compared to $24.7 million for the first half of 2011. The decrease in revenue from 2011 to 2012 is due to lower revenue recognition under the collaboration agreement with Abbott for our GnRH program, as substantially all of the workload for elagolix was transferred to Abbott.

During the second quarter and six months ended June 30, 2012 the Company recognized $1.2 million and $2.6 million, respectively, in revenue from internal and external research and development expense reimbursement under its Abbott collaboration agreement. This compares to internal and external research and development expense reimbursement revenue from Abbott of $2.5 million and $5.4 million during the second quarter of 2011 and six months ended June 30, 2011, respectively.

Research and development expenses were $8.8 million during the second quarter of 2012 compared to $8.2 million for the same period in 2011. For the six months ended June 30, 2012, research and development expenses were $18.2 million, compared to $15.5 million for the same period last year. The increase in research and development expenses is primarily due to increased personnel related costs and share-based compensation expense. Additionally, higher year-to-date external development costs related to the VMAT2 program were partially offset by a decrease in elagolix external development expenses as a result of the continued transition of elagolix development work to Abbott.

General and administrative expenses were $3.1 million for the second quarter of 2012 and $2.8 million during the same period last year. For the six months ended June 30, 2012, general and administrative expenses were $6.8 million, compared to $6.0 million for the first half of 2011. The increase in general and administrative expenses is primarily due to higher share-based compensation expense.

Pipeline Highlights

Elagolix Update

Abbott launched the initial Phase III study during the second quarter of 2012. The study is a 24-week, multinational, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of elagolix in 875 women, age 18 to 49, with moderate-to-severe endometriosis-associated pain. The initial Phase III study is currently being conducted at approximately 160 sites in the United States, Puerto Rico and Canada.

Abbott is conducting a Phase III study of elagolix in uterine fibroids to assess blood loss in women with heavy uterine bleeding due to such fibroids.

VMAT2 Update

The Company is moving its VMAT2 inhibitor, NBI-98854, into Phase IIb clinical trials. An investigator meeting will be held in early August for a large Phase IIb trial which will begin screening in the third quarter of 2012. This placebo-controlled, double-blind, parallel design, multiple dose, 12 week study will assess six week dosing of NBI-98854, against placebo, followed by six weeks of active treatment with NBI-98854. The study will also incorporate a capsule formulation of NBI-98854. Top-line data from this study

is expected in the first quarter of 2013.

Conference Call and Webcast Today at 5:00PM 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 800-862-9098 (US) or 785-424-1051 (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 ir@neurocrine.com. A replay of the conference call will be available approximately one hour after the conclusion of the call by dialing 800-695-0671 (US) or 402-220-1397 (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 the ongoing Phase III endometriosis clinical trial for elagolix, the most advanced clinical program in the Company's pipeline, will fail to support the additional Phase III clinical trial required for regulatory approval; risk that the elagolix Phase III program overall will encounter delays for regulatory or other reasons; risk that the elagolix Phase III clinical program will fail to demonstrate that elagolix is safe and effective for the treatment of endometriosis or support filings for regulatory approval; risk that the uterine fibroid elagolix clinical trials will fail to demonstrate that elagolix is safe and effective for the treatment of uterine fibroids; 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 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, 2011 and report on Form 10-Q for the quarter ended March 31, 2012. 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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenues:				
Sponsored research and development	$ 1,540	$ 2,919	$ 3,569	$ 6,193
Milestones and license fees	9,029	9,238	18,267	18,476
Total revenues	10,569	12,157	21,836	24,669
Operating expenses:				
Research and development	8,818	8,176	18,206	15,493
General and administrative	3,131	2,809	6,802	5,965
Cease-use expense	-	76	-	176
Total operating expenses	11,949	11,061	25,008	21,634
(Loss) income from operations	(1,380)	1,096	(3,172)	3,035
Other income:				

Gain on sale/disposal of assets	-	18	25	98
Deferred gain on real estate	759	737	1,517	1,473
Investment income, net	115	120	236	239
Other income, net	5	5	7	13
Total other income	879	880	1,785	1,823
Net (loss) income	$ (501)	$ 1,976	$ (1,387)	$ 4,858
Net (loss) income per common share:				
Basic	$ (0.01)	$ 0.04	$ (0.02)	$ 0.09
Diluted	$ (0.01)	$ 0.04	$ (0.02)	$ 0.09
Shares used in the calculation of net (loss) income per common share:				
Basic	66,309	55,209	64,857	55,097
Diluted	66,309	56,434	64,857	56,276

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

	June 30, 2012	December 31, 2011
Cash, cash equivalents and short-term marketable securities	$ 177,540	$ 129,103
Other current assets	3,718	3,373
Total current assets	181,258	132,476
Property and equipment, net	1,861	1,586
Long-term investments	14,634	—
Restricted cash	4,334	4,306
Total assets	$ 202,087	$ 138,368
Current liabilities	$ 29,152	$ 47,110
Long-term liabilities	28,202	31,177
Stockholders' equity	144,733	60,081
Total liabilities and stockholders' equity	$ 202,087	$ 138,368

SOURCE Neurocrine Biosciences, Inc.

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