Neurocrine Biosciences Reports Fourth Quarter And Year End 2012 Results

February 8, 2013

ANNOUNCES 2013 CLINICAL MILESTONES FOR RAPIDLY MATURING R&D PIPELINE

SAN DIEGO, Feb. 8, 2013 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its financial results for the quarter and year ended December 31, 2012.

For the fourth quarter of 2012, the Company reported net income of $9.5 million, or $0.14 per fully diluted share, compared to net income of $1.3 million, or $0.02 per fully diluted share, for the same period in 2011. For the year ended December 31, 2012, the Company reported net income of $5.0 million, or $0.08 per fully diluted share, as compared to net income of $37.6 million, or $0.67 per fully diluted share, for 2011. One-time milestone payments of $30.0 million during 2011 were primarily responsible for the change in operating results year over year.

The Company's balance sheet at December 31, 2012 reflected total assets of $196.0 million, including cash, investments and receivables of $188.3 million compared with balances at December 31, 2011 of $138.4 million and $131.7 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 $83.0 million.

"During 2012 we continued to perform to financial plan and were successful in moving our VMAT2 tardive dyskinesia program forward, as well as AbbVie advancing the elagolix endometriosis and uterine fibroids programs," said Kevin C. Gorman, President and CEO of Neurocrine Biosciences. "Looking to 2013 we will have two Phase IIb readouts for our VMAT2 program, expect AbbVie to progress elagolix into Phase IIb in uterine fibroids, and we anticipate one additional program entering the clinic, resulting in a very productive year."

Revenues for the fourth quarter of 2012 were $21.9 million, compared to $11.1 million for the same period in 2011. The $10.8 million increase in revenue is primarily due to higher revenues under the Company's elagolix collaboration agreement. Revenues for the year ended December 31, 2012 were $53.1 million, compared with $77.4 million for 2011. The $24.3 million decrease in revenue is primarily due to $30 million in milestones achieved under the Company's elagolix collaboration agreement during the third quarter of 2011.

Research and development expenses increased to $9.1 million during the fourth quarter of 2012 compared with $8.0 million for the same period in 2011. For the year ended December 31, 2012, research and development expenses were $37.2 million, compared to $31.0 million for 2011. The increase in research and development expenses is primarily driven by Phase IIb development expenses for the VMAT2 program, coupled with increased compensation related costs, primarily due to equity based compensation.

General and administrative expenses increased to $3.3 million during the fourth quarter of 2012 compared with $2.7 million for the same period last year. For the year ended December 31, 2012, general and administrative expenses were $13.4 million, compared to $12.5 million for 2011. The increase in year-to-date general and administrative expenses is primarily related to higher equity based compensation costs.

2013 Financial Guidance

The Company expects to have a net cash burn from operations of approximately $50 to $55 million in 2013. Revenue is expected to approximate $3 million which consists solely of the amortization of up-front license fees. Expenses for 2013 should approximate $55 to $60 million. Net loss for 2013 is expected to be $50 to $55 million, or $0.75 to $0.83 loss per share based on 66.5 million basic shares outstanding. The Company expects to end 2013 with in excess of $130 million in cash, investments and receivables.

Pipeline Highlights

Elagolix Update

AbbVie is currently conducting the initial Phase III study of elagolix for endometriosis, the Violet Petal Study. 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. Approximately 160 sites in the United States, Puerto Rico and Canada are conducting this study.

AbbVie is also currently conducting a Phase II study of elagolix for uterine fibroids to assess blood loss in women with heavy

uterine bleeding due to such fibroids. AbbVie expects a Phase IIb study in uterine fibroids to commence in 2013.

VMAT2 Update

The Company is currently conducting two Phase IIb studies of its VMAT2 inhibitor NBI-98854.

The Kinect Study is a 120 subject, placebo-controlled, double-blind, parallel design, multiple dose, 12-week study assessing six-week dosing of NBI-98854 against placebo, followed by six weeks of open-label treatment with NBI-98854. The primary endpoint is the Abnormal Involuntary Movement Scale (AIMS) at the end of the first six weeks of dosing. The study will also incorporate a capsule formulation of NBI-98854. Top-line data from the placebo-controlled portion of this study is expected in the second quarter of 2013.

The Kinect 2 Study is a 90 subject, placebo-controlled, double-blind, parallel design, multiple dose, six-week study assessing NBI-98854 against placebo. The primary endpoint is the AIMS at the end of the six weeks of dosing. Top-line data from this placebo-controlled study is expected in the third quarter of 2013.

Additionally, the Company is conducting appropriate preclinical studies to support the advancement of NBI-98854 into clinical trials for individuals suffering from Tourette's syndrome.

The Company anticipates and end-of-phase-II meeting for NBI-98854 in tardive dyskinesia to be held with the FDA in the fourth quarter of 2013.

Conference Call and Webcast Today at 8:00 AM Eastern Time

Neurocrine will hold a live conference call and webcast today at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time). Participants can access the live conference call by dialing 866-952-1906 (US) or 785-424-1825 (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 800-388-6197 (US) or 402-220-1115 (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, tardive dyskinesia, uterine fibroids, stress-related disorders, pain, 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 NBI-98854 will not proceed to later stage clinical trials and risk that the Company's clinical trials will fail to demonstrate that NBI-98854 is safe and effective; 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 Form 10-Q for the quarter ended September 30, 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 December 31,		Year Ended December 31,	
	2012	2011	2012	2011
Revenues:				
Sponsored research and development	$ 13,959	$ 1,873	$ 18,897	$ 10,462
Milestones and license fees	7,988	9,237	34,243	66,951
Total revenues	21,947	11,110	53,140	77,413
Operating expenses:				
Research and development	9,097	8,002	37,163	30,951
General and administrative	3,311	2,668	13,437	12,458
Cease-use expense	957	(7)	1,092	82
Total operating expenses	13,365	10,663	51,692	43,491
Income from operations	8,582	447	1,448	33,922
Other income:				
Gain on sale/disposal of assets	7	58	32	242
Deferred gain on real estate	766	744	3,042	2,953
Investment income, net	130	77	489	418
Other income, net	5	5	14	36
Total other income	908	884	3,577	3,649
Net income	$ 9,490	$ 1,331	$ 5,025	$ 37,571
Net income per common share:				
Basic	$ 0.14	$ 0.02	$ 0.08	$ 0.68
Diluted	$ 0.14	$ 0.02	$ 0.08	$ 0.67
Shares used in the calculation of net income per common share:				
Basic	66,406	55,259	65,619	55,176
Diluted	67,720	56,461	66,946	56,347

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

	December 31, 2012	December 31, 2011
Cash, cash equivalents and short-term marketable securities	$ 173,013	$ 129,103
Other current assets	16,251	3,373
Total current assets	189,264	132,476
Property and equipment, net	1,900	1,586
Long-term investments	480	—
Restricted cash	4,335	4,306
Total assets	$ 195,979	$ 138,368
Current liabilities	$ 15,646	$ 47,110
Long-term liabilities	25,961	31,177
Stockholders' equity	154,372	60,081

Total liabilities and stockholders' equity	$ 195,979	$ 138,368

SOURCE Neurocrine Biosciences, Inc.

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