



## Neurocrine Biosciences Reports Third Quarter 2012 Results

October 31, 2012

### VMAT2 Phase IIb Program Initiated With KINECT Study

SAN DIEGO, Oct. 31, 2012 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter and nine months ended September 30, 2012. For the third quarter of 2012, the Company reported a net loss of \$3.1 million, or \$0.05 loss per share, compared to net income of \$31.4 million, or income of \$0.56 per fully diluted share outstanding, for the same period in 2011. For the nine months ended September 30, 2012, the Company reported a net loss of \$4.5 million, or \$0.07 loss per share, compared to net income of \$36.2 million, or income of \$0.64 per fully diluted share outstanding, for the first nine months of last year. During the third quarter of 2011, the Company recognized \$30.0 million in milestone revenue under its collaboration agreement with Abbott.

The Company's balance sheet at September 30, 2012 reflected cash, cash equivalents, investments and receivables under collaboration agreements of \$185.5 million.

"Neurocrine continued to advance its development pipeline with our VMAT2 inhibitor entering Phase IIb clinical trials this past quarter," said Christopher O'Brien, Chief Medical Officer of Neurocrine Biosciences. "The KINECT study, along with the pending second Phase IIb study of NBI-98854 in tardive dyskinesia patients as well as information from the elagolix program will provide significant data flow over the coming quarters."

"Significant progress has also been made with elagolix," said Kevin Gorman, Chief Executive Officer of Neurocrine Biosciences. "The Phase III study for elagolix in endometriosis is enrolling as planned, and the Phase II clinical trial in uterine fibroids is anticipated to complete in the first half of next year."

Revenues for the third quarter of 2012 were \$9.4 million, compared to \$41.6 million for the same period in 2011. Revenues for the nine months ended September 30, 2012 were \$31.2 million, compared to \$66.3 million for the first nine months of 2011. The decrease in revenue from 2011 to 2012 is primarily due to \$30.0 million in milestones which were achieved under the Company's collaboration agreement with Abbott during the third quarter of 2011. Sponsored research and development revenue has also decreased as substantially all of the Phase III workload for elagolix has been transferred to Abbott.

Research and development expenses were \$9.9 million during the third quarter of 2012 compared to \$7.5 million for the same period in 2011. For the nine months ended September 30, 2012, research and development expenses were \$28.1 million, compared to \$22.9 million for the same period last year. The increase in research and development expenses is primarily due to higher year-to-date external development costs related to the Phase II development of the VMAT2 program coupled with increased personnel related costs and share-based compensation expense. These increases 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 \$3.3 million for the third quarter of 2012 and \$3.8 million during the same period last year. The decrease in general and administrative expenses is primarily due to one-time severance costs incurred during the third quarter of 2011. For the nine months ended September 30, 2012, general and administrative expenses were \$10.1 million, compared to \$9.8 million for the same period last year. The increase in year-to-date general and administrative expenses is primarily due to higher share-based compensation expense.

### ***Pipeline Highlights***

#### **Elagolix Update**

Abbott launched the initial Phase III study, the Violet Petal 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. Approximately 160 sites in the United States, Puerto Rico and Canada are conducting this study.

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

#### **VMAT2 Update**

During the third quarter, the Company began screening subjects in a Phase IIb clinical trial of its VMAT2 inhibitor, NBI-98854. The

KINECT Study is a 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.

A second Phase IIb study of NBI-98854 in tardive dyskinesia patients is planned to start during the fourth quarter of 2012. This randomized, parallel, placebo-controlled, double-blind study will assess moderate to severe tardive dyskinesia sufferers with underlying mood disorders, schizophrenia and schizoaffective disorders, and gastrointestinal disorders.

### **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 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 [ir@neurocrine.com](mailto:ir@neurocrine.com). A replay of the conference call will be available approximately one hour after the conclusion of the call by dialing 800-723-5782 (US) or 402-220-2663 (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 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 June 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		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Revenues:				
Sponsored research and development	\$ 1,369	\$ 2,396	\$ 4,938	\$ 8,589
Milestones and license fees	7,988	39,238	26,255	57,714
Total revenues	9,357	41,634	31,193	66,303
Operating expenses:				
Research and development	9,860	7,456	28,066	22,949
General and administrative	3,324	3,825	10,126	9,790

Cease-use expense	135	(87)	135	89
Total operating expenses	13,319	11,194	38,327	32,828
(Loss) income from operations	(3,962)	30,440	(7,134)	33,475
Other income:				
Gain on sale/disposal of assets	—	86	26	184
Deferred gain on real estate	759	736	2,275	2,209
Investment income, net	123	102	359	341
Other income, net	2	18	9	31
Total other income	884	942	2,669	2,765
Net (loss) income	<u>\$ (3,078)</u>	<u>\$ 31,382</u>	<u>\$ (4,465)</u>	<u>\$ 36,240</u>
Net (loss) income per common share:				
Basic	<u>\$ (0.05)</u>	<u>\$ 0.57</u>	<u>\$ (0.07)</u>	<u>\$ 0.66</u>
Diluted	<u>\$ (0.05)</u>	<u>\$ 0.56</u>	<u>\$ (0.07)</u>	<u>\$ 0.64</u>
Shares used in the calculation of net (loss) income per common share:				
Basic	<u>66,342</u>	<u>55,248</u>	<u>65,355</u>	<u>55,148</u>
Diluted	<u>66,342</u>	<u>56,378</u>	<u>65,355</u>	<u>56,309</u>

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

	<b>September 30, December 31,</b>	
	<b>2012</b>	<b>2011</b>
Cash, cash equivalents and short-term marketable securities	\$ 173,961	\$ 129,103
Other current assets	4,057	3,373
Total current assets	178,018	132,476
Property and equipment, net	2,034	1,586
Long-term investments	8,865	—
Restricted cash	4,334	4,306
Total assets	<u>\$ 193,251</u>	<u>\$ 138,368</u>
Current liabilities	\$ 23,113	\$ 47,110
Long-term liabilities	26,833	31,177
Stockholders' equity	143,305	60,081
Total liabilities and stockholders' equity	<u>\$ 193,251</u>	<u>\$ 138,368</u>

SOURCE Neurocrine Biosciences, Inc.

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