



## Neurocrine Biosciences Reports Second Quarter 2011 Results

July 28, 2011

### VMAT2 PROGRAM CONTINUES TO PROGRESS

SAN DIEGO, July 28, 2011 /PRNewswire via COMTEX/ --Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its financial results for the quarter ended June 30, 2011. For the second quarter of 2011, the Company reported net income of \$2.0 million, or \$0.04 per share, compared to a net loss of \$5.2 million, or \$0.09 loss per share, for the same period in 2010. For the six months ended June 30, 2011, the Company reported net income of \$4.9 million, or \$0.09 per share, as compared to a net loss of \$13.8 million, or \$0.27 loss per share, for the first half of last year.

The Company's balance sheet at June 30, 2011 reflected total assets of \$127.4 million, including cash, cash equivalents, investments and receivables under collaboration agreements of \$118.1 million compared to balances at December 31, 2010 of \$144.4 million and \$135.1 million, respectively.

"Our financial results for the second quarter of 2011 were consistent with our budget, and our cash target for the quarter was met," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "Our partner Abbott continues to advance the elagolix program in both endometriosis and uterine fibroids, our VMAT2 program also took two significant steps forward during this past quarter. In June, we met with the FDA in a pre-IND meeting for our VMAT2 inhibitor, and based on that successful meeting we submitted our IND in July. Additionally, at the end of the second quarter we were notified that the United States Patent and Trademark Office had approved our composition of matter patent application for NBI-98854, our VMAT2 inhibitor."

Revenues for the second quarter of 2011 were \$12.2 million, compared to \$4.6 million for the same period in 2010. Revenues for the six months ended June 30, 2011 were \$24.7 million, compared to \$5.4 million for the first half of 2010. The increase in revenue from 2010 to 2011 is due to a full period 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.

During the second quarter of 2011, the Company recognized \$8.6 million of revenue from amortization of up-front licensing fees and \$2.9 million in revenue from internal and external research and development expense reimbursement under its Abbott and Boehringer Ingelheim collaboration agreements. This compares to revenue of \$2.6 million from amortization of up-front license fees and \$1.3 million resulting from internal and external research and development expense reimbursements during the second quarter of 2010.

Revenue recognized from amortization of up-front license fees under the Abbott and Boehringer Ingelheim agreements for the first half of 2011 was \$17.0 million compared to \$2.6 million in 2010. Sponsored research and development revenue was \$6.2 million for the first six months of 2011, compared to \$1.3 million for the first half of 2010.

During each of the three and six month periods ended June 30, 2011 and 2010, the Company recognized revenue of \$0.7 million and \$1.5 million, respectively, from amortization of up-front licensing fees under our collaboration agreement for indiplon with Dainippon Sumitomo Pharma Co. Ltd.

Research and development expenses increased to \$8.2 million during the second quarter of 2011 compared to \$7.3 million for the same period in 2010. For the six months ended June 30, 2011, research and development expenses were \$15.5 million, compared to \$14.9 million for the same period last year. The increase in research and development expenses is primarily due to increased personnel and scientific consulting costs. These costs were offset by lower external development costs related to elagolix, as a result of the transition of development work to Abbott.

General and administrative expenses were \$2.8 million for the second quarter of 2011 and \$3.1 million during the same period last year. For the six months ended June 30, 2011, general and administrative expenses were \$6.0 million, compared to \$6.3 million for the first half of 2010. The decrease in general and administrative expenses is primarily due to lower facility related costs.

Other income increased to \$0.9 million during the second quarter of 2011 from \$0.7 million of income for the second quarter of 2010. Other income decreased from \$2.3 million of income during the first half of 2010 to \$1.8 million of income for the first half of 2011. The decrease in year-to-date other income resulted from a \$0.5 million realized gain on the sale of auction rate securities in the first quarter of 2010.

### **Pipeline Highlights**

## **Elagolix Update**

Elagolix Phase III trials for endometriosis are planned to start in the fourth quarter of 2011, with Phase II trials assessing elagolix in uterine fibroids expected to start in the third quarter of 2011.

Additionally, multiple abstracts and datasets from the development program of elagolix for endometriosis will be presented at the 2011 World Congress on Endometriosis to be held September 4-7, 2011 in Montpellier, France.

## **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 with the FDA Division of Psychiatry.

A second Phase II study is expected to be initiated in the United States in September of this year to further assess NBI-98854 in tardive dyskinesia patients. The design of this 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 will assess once-daily NBI-98854 (12.5mg and 50mg) over a two week dosing period. The primary endpoint of the study will be the Abnormal Involuntary Movement Scale (AIMS).

The Company has also started three-month in-vivo toxicology studies to support longer dosing regimens. This data is also expected during the fourth quarter of 2011. Pending the results of this toxicology study and the second Phase II study, a larger, Phase IIb study is planned to be initiated in early 2012 to assess three-month dosing of NBI-98854.

## **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 45 patients as of mid-July, 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. 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 Tomorrow at 8:00AM Eastern Time**

Neurocrine will hold a live conference call and webcast tomorrow at 8:00 a.m. Eastern Time (5:00 a.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: 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 800-283-8520 (US) or 402-220-0870(International) using the conference ID: 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, 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 elagolix, the company's lead clinical program, will fail to demonstrate that elagolix is safe and effective; risk that elagolix Phase III clinical trials will be delayed for regulatory or other reasons; 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 March 31, 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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenues:				
Sponsored research and development	\$ 2,919	\$ 1,286	\$ 6,193	\$ 1,309
Milestones and license fees	9,238	3,357	18,476	4,087
Total revenues	12,157	4,643	24,669	5,396
Operating expenses:				
Research and development	8,176	7,283	15,493	14,859
General and administrative	2,809	3,116	5,965	6,315
Cease-use expense	76	134	176	281
Total operating expenses	11,061	10,533	21,634	21,455
Income (loss) from operations	1,096	(5,890)	3,035	(16,059)
Other income:				
Gain on sale/disposal of assets	18	53	98	168
Deferred gain on real estate	737	715	1,473	1,430
Investment income and (expense), net	120	(65)	239	614
Other income, net	5	35	13	59
Total other income	880	738	1,823	2,271
Net income (loss)	\$ 1,976	\$ (5,152)	\$ 4,858	\$ (13,788)
Net income (loss) per common share:				
Basic	\$ 0.04	\$ (0.09)	\$ 0.09	\$ (0.27)
Diluted	\$ 0.04	\$ (0.09)	\$ 0.09	\$ (0.27)
Shares used in the calculation of net income (loss) per common share:				
Basic	55,209	54,836	55,097	50,750
Diluted	56,434	54,836	56,276	50,750

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

	June 30, 2011	December 31, 2010
Cash, cash equivalents and short-term marketable securities	\$ 115,160	\$ 126,865

Other current assets	4,878	6,186
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Total current assets	120,038	133,051
Property and equipment, net	1,263	1,532
Long-term investments	--	3,739
Restricted cash	6,104	6,102
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Total assets	<u>\$ 127,405</u>	<u>\$ 144,424</u>
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Current liabilities	\$ 49,990	\$ 52,777
Long-term liabilities	51,857	72,302
Stockholders' equity	25,558	19,345
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Total liabilities and stockholders' equity	<u>\$ 127,405</u>	<u>\$ 144,424</u>

SOURCE Neurocrine Biosciences, Inc.