



## Neurocrine Biosciences Reports Third Quarter 2011 Results

October 31, 2011

### COMPANY RECEIVES \$30 MILLION IN MILESTONES DURING THE QUARTER

SAN DIEGO, Oct. 31, 2011 /PRNewswire via COMTEX/ --

Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended September 30, 2011.

For the third quarter of 2011, the Company reported net income of \$31.4 million, or \$0.56 per fully diluted share outstanding, compared to net income of \$3.3 million, or \$0.06 per fully diluted share outstanding, for the same period in 2010. For the nine months ended September 30, 2011, the Company reported a net income of \$36.2 million, or \$0.64 per fully diluted share outstanding, as compared to a net loss of \$10.5 million, or \$0.20 loss per basic share outstanding, for the same period last year.

The Company's balance sheet on September 30, 2011 reflected total assets of \$149.0 million, including cash, investments and receivables of \$140.2 million. The asset balances were bolstered during the third quarter through \$30.0 million of milestones recognized under the Abbott collaboration agreement.

"The achievement of the two milestones under the Abbott agreement enables us to achieve our \$130 million 2011 year-end cash, investments and receivables target for the Company," said Timothy P. Coughlin, Chief Financial Officer of Neurocrine Biosciences. "With Abbott moving elagolix forward in endometriosis and uterine fibroids, we will look to accelerate our VMAT2 Phase II clinical program, as well as bring some of our pre-clinical drug candidates into the clinic."

Revenues for the third quarter of 2011 were \$41.6 million, compared to \$14.4 million for the same period in 2010. Revenues for the nine months ended September 30, 2011 were \$66.3 million, compared to \$19.8 million for the same period in 2010. The increase in revenue in the third quarter 2011 is due to two milestones achieved under the Company's collaboration agreement with Abbott. The Company recognized a \$10.0 million milestone which was related to advancing elagolix into Phase II clinical trials in uterine fibroids and a \$20.0 million milestone related to the outcome of an elagolix pre-Phase III meeting with the FDA for endometriosis. The increase in year-to-date revenue is a result of these milestones, as well as a full nine months 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 \$7.5 million during the third quarter of 2011 compared to \$8.2 million for the same period in 2010. Year-to-date research and development expenses for 2011 were \$22.9 million compared to \$23.1 million for the first nine months of 2010. This decrease in expense is primarily due to the continued transition of the elagolix workload from the Company to Abbott, offset by an increase in external development expenses for the Company's VMAT2 program.

General and administrative expenses increased to \$3.8 million during the third quarter of 2011 compared with \$3.6 million for the same period last year. For the nine months ended September 30, 2011, general and administrative expenses were \$9.8 million, compared to \$10.0 million for the first nine months of 2010.

Other income was \$0.9 million during the third quarter of both 2011 and 2010. Other income decreased from \$3.1 million of income during the first nine months of 2010 to \$2.8 million of other income for the first nine months of 2011. This change resulted primarily from a one-time \$0.5 million gain recognized on auction rate securities in 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 initiated in the third quarter of 2011.

Additionally, multiple abstracts and datasets from the development program of elagolix for endometriosis were presented at the 2011 World Congress on Endometriosis this past September and during the 2011 Annual Meeting of the American Society for Reproductive Medicine earlier this month.

#### **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 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 will assess 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 is currently enrolling subjects and the Company expects the results of this study in early 2012.

The Company is also conducting a three-month in-vivo toxicology study to support longer dosing regimens. This data is expected late in the fourth quarter of 2011. Pending the results of this toxicology study and the second Phase II study, a larger Phase IIb program 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. The academic center expects the final enrollment to complete shortly.

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 5:00PM 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 (858) 617-7600. A replay of the conference call will be available approximately one hour after the conclusion of the call by dialing 800-695-0974 (US) or 402-220-1459 (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 diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, stress-related disorders, pain, tardive dyskinesia, 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 the 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 June 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**  
**September 30,**

**Nine Months Ended**  
**September 30,**

	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
Revenues:				
Sponsored research and development	\$ 2,396	\$ 5,210	\$ 8,589	\$ 6,519
Milestones and license fees	<u>39,238</u>	<u>9,238</u>	<u>57,714</u>	<u>13,325</u>
Total revenues	41,634	14,448	66,303	19,844
Operating expenses:				
Research and development	7,456	8,227	22,949	23,086
General and administrative	3,825	3,635	9,790	9,950
Cease-use expense	<u>(87)</u>	<u>120</u>	<u>89</u>	<u>401</u>
Total operating expenses	<u>11,194</u>	<u>11,982</u>	<u>32,828</u>	<u>33,437</u>
Income (loss) from operations	30,440	2,466	33,475	(13,593)
Other income:				
Gain on sale/disposal of assets	86	34	184	202
Deferred gain on real estate	736	715	2,209	2,145
Investment income, net	102	118	341	732
Other income, net	<u>18</u>	<u>--</u>	<u>31</u>	<u>59</u>
Total other income	<u>942</u>	<u>867</u>	<u>2,765</u>	<u>3,138</u>
Net income (loss)	<u>\$ 31,382</u>	<u>\$ 3,333</u>	<u>\$ 36,240</u>	<u>\$ (10,455)</u>
Net income (loss) per common share:				
Basic	<u>\$ 0.57</u>	<u>\$ 0.06</u>	<u>\$ 0.66</u>	<u>\$ (0.20)</u>
Diluted	<u>\$ 0.56</u>	<u>\$ 0.06</u>	<u>\$ 0.64</u>	<u>\$ (0.20)</u>
Shares used in the calculation of net income (loss) per common share:				
Basic	<u>55,248</u>	<u>54,844</u>	<u>55,148</u>	<u>52,130</u>
Diluted	<u>56,378</u>	<u>55,648</u>	<u>56,309</u>	<u>52,130</u>

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

	<u>September 30,</u> <u>2011</u>	<u>December 31,</u> <u>2010</u>
Cash, cash equivalents and short-term marketable securities	\$ 111,631	\$ 126,865
Other current assets	<u>24,495</u>	<u>6,186</u>
Total current assets	136,126	133,051
Property and equipment, net	1,687	1,532
Long-term investments	5,087	3,739
Restricted cash	<u>6,128</u>	<u>6,102</u>
Total assets	<u>\$ 149,028</u>	<u>\$ 144,424</u>
Current liabilities	\$ 48,444	\$ 52,777
Long-term liabilities	42,835	72,302
Stockholders' equity	<u>57,749</u>	<u>19,345</u>
Total liabilities and stockholders' equity	<u>\$ 149,028</u>	<u>\$ 144,424</u>

SOURCE Neurocrine Biosciences, Inc.