Neurocrine Biosciences Reports Third Quarter 2014 Results

November 3, 2014

NBI-98854 Phase III Program Underway for Tardive Dyskinesia
Tourette Syndrome Phase IB Study Initiated
FDA Grants Breakthrough Therapy Designation for Tardive Dyskinesia

SAN DIEGO, Nov. 3, 2014 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended September 30, 2014. For the third quarter of 2014, the Company reported a net loss of $15.9 million, or $0.21 loss per share, compared to a net loss of $11.1 million, or $0.17 loss per share, for the same period in 2013. For the nine months ended September 30, 2014, the Company reported a net loss of $41.1 million, or $0.56 loss per share, as compared to net loss of $35.4 million, or $0.53 loss per share, for the first three quarters of last year.

The Company's balance sheet at September 30, 2014 reflected total assets of $257.8 million, including cash, cash equivalents, investments and receivables of $248.3 million.

"We have made significant progress over the past quarter with our VMAT2 program, including the initiation of the Kinect 3 Phase III study, receiving Breakthrough Therapy Designation from the FDA for tardive dyskinesia, and starting the first clinical assessment of NBI-98854 in children with Tourette syndrome," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "We look forward to multiple clinical trial readouts in 2015 including Phase III topline efficacy data for elagolix in endometriosis and Phase IIb efficacy data for elagolix in uterine fibroids reported by our partner AbbVie, as well as Kinect 3 Phase III topline efficacy data and Phase Ib data in Tourette from our VMAT2 inhibitor."

Research and development expenses were $12.2 million during the third quarter of 2014, compared to $9.5 million for the same period in 2013. General and administrative expenses increased from $3.2 million for the third quarter of 2013 to $4.7 million for the third quarter of 2014. For the nine months ended September 30, 2014, research and development expenses were $30.9 million, compared to $30.3 million for the same period last year, while general and administrative expenses were $13.0 million, compared to $10.0 million. This increase in year-to-date expenses is primarily due to higher personnel costs, with share-based compensation expense representing $2.8 million of the year-to-date increase in expenses.

Pipeline Highlights

VMAT2 Update

The Company recently initiated a Phase III study of NBI-98854, the Kinect 3 study. The Kinect 3 study, along with the previous efficacy studies of NBI-98854, is designed to complete the placebo-controlled clinical efficacy evaluation of NBI-98854 in tardive dyskinesia. The primary endpoint in the Kinect 3 study is the mean change from baseline in the Abnormal Involuntary Movement Scale (AIMS) as assessed by blinded central raters. The Kinect 3 study will include approximately 240 subjects randomized to either placebo, once daily 40mg of NBI-98854 or once daily 80mg of NBI-98854 for six weeks of placebo-controlled dosing followed by an extension of active dosing through Week 48. The Company also intends to conduct a separate one-year open-label safety study of NBI-98854 to support the anticipated 2016 filing of a New Drug Application in tardive dyskinesia.

Top-line efficacy data from the initial six weeks of placebo-controlled dosing is expected in the second half of 2015.

The Company also recently received Breakthrough Therapy Designation from the FDA for NBI-98854 in the treatment of tardive dyskinesia.

The Company is also exploring NBI-98854 in an initial Tourette syndrome clinical trial, the T-Force study. This study is an open-label, multi-dose, two-week evaluation of 36 subjects with Tourette syndrome. Children and adolescents enrolled in the trial will receive once-daily dosing of NBI-98854 during a two-week treatment period to assess both the safety and tolerability of NBI-98854 in Tourette patients. Additionally, the Yale Global Tic Severity Scale and the Premonitory Urge for Tics Scale will be employed during the study to assess the impact of NBI-98854 on the patients' Tourette symptoms. Data readout from this study is expected in 2015.

Elagolix Update

AbbVie is currently conducting the Violet Petal Study, a Phase III study of elagolix for endometriosis. 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 which completed patient recruitment and randomization during the second quarter. Topline efficacy data from this study is anticipated to be available in January 2015.

AbbVie is also conducting the second Phase III study of elagolix for endometriosis, the Solstice Study. This study is similar in design to the Violet Petal Study and will assess 788 women, age 18 to 49, with moderate to severe endometriosis-associated pain at more than 200 sites globally.

Elagolix is also being evaluated in women with uterine fibroids. AbbVie is conducting a Phase IIb clinical trial evaluating the change in menstrual blood loss of 520 women, age 18-51, with heavy menstrual bleeding associated with uterine fibroids.

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 877-888-4314 (US) or 785-424-1875 (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 800-723-0528 (US) or 402-220-2654 (International) using the conference ID: NBIX. The call will be archived for one month.

Neurocrine Biosciences, Inc. discovers and develops innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through its novel R&D platform, focused on neurological and endocrine based diseases and disorders. The Company's two lead late-stage clinical programs are elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc., and a wholly owned vesicular monoamine transporter 2 inhibitor for the treatment of movement disorders. Neurocrine intends to maintain certain commercial rights to its VMAT2 inhibitor for evolution into a fully-integrated pharmaceutical company.

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 R&D pipeline as well as its business overall. Specifically, the risks and uncertainties the Company faces with respect to elagolix, include the risk that the elagolix endometriosis Phase III clinical trials will fail to demonstrate that elagolix is safe and effective; the risk that elagolix Phase III clinical trials will be delayed for regulatory or other reasons; the risk that the elagolix uterine fibroids clinical program will not proceed to later stage clinical trials; and the risks associated with the Company's dependence on AbbVie for elagolix 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 VMAT2 Phase III clinical program will fail to demonstrate that NBI-98854 is safe and effective; risk that the VMAT2 Phase III program will be delayed for regulatory or other reasons; risk that the Breakthrough Therapy designation may not result in an expedited development and review process for NBI-98854 and may not lead to regulatory approval; risk that the Company will be unable to complete the Tourette syndrome Phase I clinical trial for regulatory or other reasons; risk that the Company's research programs will not identify pre-clinical candidates for further development; and risk that the Company's other product candidates will not be found to be safe and effective. With respect to its business 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 contractors for clinical drug supply, 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 if approved. The Company also faces the other risks described in the Company's annual report on Form 10-K for the year ended December 31, 2013 and quarterly reports on Form 10-Q for the quarters ended March 31, 2014 and June 30, 2014. 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,	
	2014	**2013**	**2014**	**2013**
Revenues:				
License fees	$ -	$ 729	$ -	$ 2,189
Total revenues	-	729	-	2,189
Operating expenses:				
Research and development	12,194	9,490	30,927	30,330
General and administrative	4,663	3,245	13,016	10,007
Total operating expenses	16,857	12,735	43,943	40,337
Loss from operations	(16,857)	(12,006)	(43,943)	(38,148)
Other income:				
Gain (loss) on sale/disposal of assets	1	6	(4)	38
Deferred gain on real estate	805	781	2,414	2,344
Investment income, net	176	93	432	317

Other income (loss), net	-	(5)	3	1
Total other income	982	875	2,845	2,700
Net loss	$ (15,875)	$ (11,131)	$ (41,098)	$ (35,448)
Net loss per common share:				
Basic and diluted	$ (0.21)	$ (0.17)	$ (0.56)	$ (0.53)
Shares used in the calculation of net loss per common share:				
Basic and diluted	75,948	67,199	74,050	66,868

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

	September 30, 2014	December 31, 2013
Cash, cash equivalents and short-term investments, available for sale	$ 179,674	$ 145,739
Other current assets	4,194	2,723
Total current assets	183,868	148,462
Property and equipment, net	2,292	1,771
Long-term investments, available for sale	67,148	-
Restricted cash	4,443	4,443
Total assets	$ 257,751	$ 154,676
Current liabilities	$ 14,045	$ 11,699
Long-term liabilities	19,669	22,567
Stockholders' equity	224,037	120,410
Total liabilities and stockholders' equity	$ 257,751	$ 154,676

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Investor Relations, (858) 617-7600