Neurocrine Biosciences Reports Third Quarter 2013 Results

October 29, 2013

NBI-98854 PHASE IIB KINECT 2 STUDY FULLY ENROLLED, DATA IN DECEMBER 2013

SAN DIEGO, Oct. 29, 2013 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its financial results for the quarter ended September 30, 2013. For the third quarter of 2013, the Company reported a net loss of $11.1 million, or $0.17 loss per share, compared to a net loss of $3.1 million, or $0.05 loss per share, for the same period in 2012. For the nine months ended September 30, 2013, the Company reported a net loss of $35.4 million, or $0.53 loss per share, as compared to net loss of $4.5 million, or $0.07 loss per share, for the first nine months of last year. At September 30, 2013, the Company had cash, cash equivalents, investments and receivables of $158.5 million.

"Our Kinect study of NBI-98854 provided valuable information regarding dose response and endpoint assessment that we have incorporated into our Kinect 2 study and overall development plan. The Kinect 2 study has also recently completed enrollment and we will have the top-line results from this Phase IIb study in December," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "Additionally, this past quarter AbbVie initiated the second Phase III study of elagolix in endometriosis and is scheduled to have top-line data from the initial elagolix Phase III endometriosis study in 2014. Elagolix is also progressing in a Phase IIb study of uterine fibroids patients."

Revenues for the third quarter of 2013 were $0.7 million, compared to $9.4 million for the same period in 2012. Revenues for the nine months ended September 30, 2013 were $2.2 million, compared to $31.2 million for the first nine months of 2012. The entire reduction in revenue from 2012 to 2013 is due to the successful completion of the sponsored research and development phases of the Company's license agreements with both AbbVie and Boehringer Ingelheim during 2012, as scheduled.

Research and development expenses were $9.5 million during the third quarter of 2013 compared to $9.9 million for the same period in 2012. For the nine months ended September 30, 2013, research and development expenses were $30.3 million, compared to $28.1 million for the same period last year. The increase in year-to-date research and development expenses is primarily due to increased external development costs related to the Company's VMAT2 program (NBI-98854) as it continues through Phase IIb clinical development.

Updated 2013 Financial Guidance

The Company expects to end 2013 with approximately $145 million in cash, investments and receivables. The net loss for 2013 is expected to be approximately $46 to $47 million, or approximately $0.70 loss per share based on 67 million basic common shares outstanding. The previous financial guidance for 2013 was a net loss of $50 to $55 million with year-end cash, investments and receivables exceeding $130 million.

Pipeline Highlights

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.

AbbVie recently initiated the second Phase III study of elagolix for endometriosis. 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**.**

AbbVie is also currently conducting a Phase IIb study of elagolix in uterine fibroids. This study is assessing uterine blood loss in 280 women with heavy uterine bleeding due to uterine fibroids.

VMAT2 Update

The Company has completed enrollment in Kinect 2, a Phase IIb study of its VMAT2 inhibitor, NBI-98854. This study is a 90 subject, placebo-controlled, double-blind, parallel-design, multiple-dose, six-week study assessing NBI-98854 in doses up to 75mg once-a-day against placebo in tardive dyskinesia patients with underlying mood disorders, schizophrenia and schizoaffective disorders, and gastrointestinal disorders. The primary endpoint is the Abnormal Involuntary Movement Scale (AIMS) at the end of

the six weeks of dosing. The video AIMS will be scored by blinded central reviewers who are movement disorder neurologists. This study recently completed screening and randomization of subjects, and top-line data from this study is expected in December of 2013.

In 2014, the Company intends to initiate another clinical study of NBI-98854 in tardive dyskinesia patients. This study is currently in the design phase, and the results of the Kinect and Kinect 2 Studies will serve to inform the ultimate design of this clinical trial. The primary endpoint in this study will be the AIMS assessed by blinded central reviewers who are movement disorder neurologists.

The Company is currently completing two Phase I studies for NBI-98854 assessing drug-drug interactions as well as the impact of hepatic impairment on drug metabolism.

Additionally, the Company is conducting preclinical studies to support the advancement of NBI-98854 into clinical trials for individuals suffering from Tourette's syndrome. Upon successful completion of these preclinical studies, the Company anticipates entering Phase I and Phase II clinical studies in 2014.

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 866-952-7534 (US) or 785-424-1835 (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 800-839-2385 (US) or 402-220-7203 (International) using the conference ID: NBIX. The call will be archived for one month.

Neurocrine Biosciences, Inc. is a clinical stage drug discovery company primarily focused on neurological and endocrine based diseases and disorders. The Company discovers and develops innovative pharmaceuticals, in diseases with high unmet medical needs or where the existing drug classes are inadequate, through a disciplined yet entrepreneurial process. Utilizing a portfolio approach to drug discovery, Neurocrine has multiple small molecule drug candidates at various stages of pharmaceutical development. Neurocrine's two lead late stage clinical programs are elagolix, a GnRH antagonist for women's health that is partnered with AbbVie Inc., and a wholly owned VMAT2 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 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. Similarly, the Company faces risk that the clinical studies for NBI-98854, the company's VMAT2 inhibitor candidate, will fail to demonstrate that NBI-98854 is safe and effective; risk that NBI-98854 Phase II clinical trials will be delayed for regulatory or other reasons; and risk that NBI-98854 will not proceed to later stage clinical trials. 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; 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, 2012 and report on Form 10-Q for the quarters ended March 31, 2013 and June 30, 2013. 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,

	2013	2012	2013	2012
Revenues:				
Sponsored research and development	$ -	$ 1,369	$ -	$ 4,938
License fees	729	7,988	2,189	26,255
Total revenues	729	9,357	2,189	31,193
Operating expenses:				
Research and development	9,490	9,860	30,330	28,066
General and administrative	3,245	3,324	10,007	10,126
Cease-use expense	-	135	-	135
Total operating expenses	12,735	13,319	40,337	38,327
Loss from operations	(12,006)	(3,962)	(38,148)	(7,134)
Other income:				
Gain on sale/disposal of assets	6	-	38	25
Deferred gain on real estate	781	759	2,344	2,276
Investment income, net	93	123	317	359
Other (loss) income, net	(5)	2	1	9
Total other income	875	884	2,700	2,669
Net loss	$ (11,131)	$ (3,078)	$ (35,448)	$ (4,465)
Net loss per common share:				
Basic and diluted	$ (0.17)	$ (0.05)	$ (0.53)	$ (0.07)
Shares used in the calculation of net loss per common share:				
Basic and diluted	67,199	66,342	66,868	65,355

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

	September 30, 2013	December 31, 2012
Cash, cash equivalents and short-term marketable securities	$ 156,911	$ 173,013
Other current assets	2,307	16,251
Total current assets	159,218	189,264
Property and equipment, net	1,739	1,900
Long-term investments	675	480
Restricted cash	4,335	4,335
Total assets	$ 165,967	$ 195,979
Current liabilities	$ 13,321	$ 15,646
Long-term liabilities	23,354	25,961
Stockholders' equity	129,292	154,372
Total liabilities and stockholders' equity	$ 165,967	$ 195,979

SOURCE Neurocrine Biosciences, Inc.

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