Neurocrine Biosciences Reports Second Quarter 2013 Results

July 25, 2013

VMAT2 PHASE IIB KINECT STUDY FULLY ENROLLED, TOP-LINE DATA IN SEPTEMBER

SAN DIEGO, July 25, 2013 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended June 30, 2013. For the second quarter of 2013, the Company reported a net loss of $12.2 million, or $0.18 loss per share, compared to a net loss of $0.5 million, or $0.01 loss per share, for the same period in 2012. For the six months ended June 30, 2013, the Company reported a net loss of $24.3 million, or $0.36 loss per share, as compared to net loss of $1.4 million, or $0.02 loss per share, for the first half of last year.

The Company's balance sheet at June 30, 2013 reflected total assets of $174.8 million, including cash, cash equivalents, investments and receivables of $167.5 million compared with balances at December 31, 2012 of $196.0 million and $188.3 million, respectively.

"While our partner AbbVie drives elagolix forward in late stage clinical trials of both endometriosis and uterine fibroids, we are very pleased with the recent progress of our wholly-owned VMAT2 program," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "NBI-98854 recently achieved a significant milestone with the completion of randomization in the Kinect Study and we look forward to sharing the top-line placebo-controlled results in September. Additionally, the Kinect 2 Study continues to enroll high quality patients and we anticipate having the top-line placebo-controlled results from this study in the fourth quarter of this year."

Revenues for the second quarter of 2013 were $0.7 million, compared to $10.6 million for the same period in 2012. Revenues for the six months ended June 30, 2013 were $1.5 million, compared to $21.8 million for the first half of 2012. The entire reduction in revenue from 2012 to 2013 is due to the successful completion of the sponsored research and development segments of the Company's license agreements with both AbbVie and Boehringer Ingelheim during 2012, as scheduled.

Research and development expenses were $10.5 million during the second quarter of 2013 compared to $8.8 million for the same period in 2012. For the six months ended June 30, 2013, research and development expenses were $20.8 million, compared to $18.2 million for the same period last year. The increase in 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.

Pipeline Highlights

Elagolix Update

AbbVie is currently conducting the initial Phase III study of elagolix for endometriosis, the Violet Petal Study. 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 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.

The manuscript for the elagolix Daisy Petal Study (901 study) entitled "Elagolix, an oral GnRH antagonist for endometriosis-associated pain: a randomized controlled study" has been accepted for future print publication in the Journal of Endometriosis and Pelvic Pain Disorders. The electronic version of the manuscript is currently available from this quarterly peer reviewed journal.

VMAT2 Update

The Company is currently conducting two Phase IIb studies of its VMAT2 inhibitor, NBI-98854.

The Kinect Study completed enrollment in early July 2013. The 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 in tardive dyskinesia patients with underlying schizophrenia or schizoaffective disorder. The primary endpoint is the Abnormal Involuntary Movement Scale (AIMS) at the end of the first six weeks of dosing. The study has incorporated a capsule formulation of NBI-98854. Top-line data from the placebo-controlled portion of this study is expected in September 2013.

The Kinect 2 Study is a 90 subject, placebo-controlled, double-blind, parallel-design, multiple-dose, six-week study assessing NBI-98854 against placebo in tardive dyskinesia patients with underlying mood disorders, schizophrenia and schizoaffective disorders, and gastrointestinal disorders. The primary endpoint is the AIMS at the end of the six weeks of dosing. This study continues to enroll patients, and top-line data from this study is expected in the fourth quarter of 2013.

The Company plans to request an end of Phase II meeting with the FDA for NBI-98854 in tardive dyskinesia during the fourth quarter of 2013.

The Company is also in the process of initiating two Phase I studies for NBI-98854 assessing drug-drug interactions as well as the impact of hepatic impairment on drug metabolism. Both of these studies will be completed prior to the start of Phase III and will support the planned NDA filing.

Additionally, the Company has initiated 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 866-952-1906 (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. A replay of the conference call will be available approximately one hour after the conclusion of the call by dialing 800-723-0488 (US) or 402-220-2651 (International) using the conference ID: NBIX. The call will be archived for two weeks.

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. 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, 2012 and report on Form 10-Q for the quarter ended March 31, 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 June 30,		Six Months Ended June 30,	
	2013	**2012**	**2013**	**2012**
Revenues:				

Sponsored research and development	$ -	$ 1,540	$ -	$ 3,569
Milestones and license fees	730	9,029	1,460	18,267
Total revenues	730	10,569	1,460	21,836
Operating expenses:				
Research and development	10,527	8,818	20,840	18,206
General and administrative	3,370	3,131	6,762	6,802
Total operating expenses	13,897	11,949	27,602	25,008
Loss from operations	(13,167)	(1,380)	(26,142)	(3,172)
Other income:				
Gain on sale/disposal of assets	19	-	32	25
Deferred gain on real estate	781	759	1,563	1,517
Investment income, net	121	115	224	236
Other income, net	4	5	6	7
Total other income	925	879	1,825	1,785
Net loss	$ (12,242)	$ (501)	$ (24,317)	$ (1,387)
Net loss per common share:				
Basic and diluted	$ (0.18)	$ (0.01)	$ (0.36)	$ (0.02)
Shares used in the calculation of net loss per common share:				
Basic and diluted	66,799	66,309	66,700	64,857

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

	June 30, 2013	December 31, 2012
Cash, cash equivalents and short-term marketable securities	$ 153,696	$ 173,013

Other current assets	2,157	16,251
Total current assets	155,853	189,264
Property and equipment, net	1,876	1,900
Long-term investments	12,749	480
Restricted cash	4,335	4,335
Total assets	$ 174,813	$ 195,979
Current liabilities	$ 14,573	$ 15,646
Long-term liabilities	24,224	25,961
Stockholders' equity	136,016	154,372
Total liabilities and stockholders' equity	$ 174,813	$ 195,979

SOURCE Neurocrine Biosciences, Inc.

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