Neurocrine Biosciences Reports First Quarter 2013 Results

May 2, 2013

ELAGOLIX ENTERS PHASE IIB FOR UTERINE FIBROIDS, ENDOMETRIOSIS PHASE III PROGRAM ON TRACK

SAN DIEGO, May 2, 2013 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended March 31, 2013. For the first quarter of 2013, the Company reported net loss of $12.1 million, or $0.18 loss per share, compared to a net loss of $0.9 million, or $0.01 loss per share, for the same period in 2012. This $11.2 million change in operating results is primarily due to lower revenue recognized during 2013 under the Company's license agreements with AbbVie and Boehringer Ingelheim. The sponsored research and development segments of both of these agreements concluded, as scheduled, during 2012.

The Company's balance sheet at March 31, 2013 reflected total assets of $183.9 million, including cash, cash equivalents, investments and receivables of $176.9 million compared with balances at December 31, 2012 of $196.0 million and $188.3 million, respectively.

"AbbVie has made great progress with elagolix. The initiation of this Phase IIb study in uterine fibroids is another significant milestone for this program," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "Our VMAT2 program also continues to move forward in two Phase IIb tardive dyskinesia studies, with an End of Phase II FDA meeting anticipated later this year."

Revenues for the first quarter of 2013 were $0.7 million compared with $11.3 million for the same period last year. The entire $10.6 million reduction in revenue 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 increased to $10.3 million during the first quarter of 2013 from $9.4 million during the same period in 2012. This increase was primarily a result of higher external clinical development expenses related to the ongoing Phase IIb studies of the Company's VMAT2 inhibitor, NBI-98854. General and administrative expenses decreased from $3.7 million in the first quarter of 2012 to $3.4 million for the first quarter of 2013, primarily due to lower professional services costs and continued cost mitigation efforts.

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.

During March 2013, AbbVie initiated 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 is currently conducting two Phase IIb studies of its VMAT2 inhibitor, NBI-98854.

The Kinect Study is a 120 subject, 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 will also incorporate a capsule formulation of NBI-98854. Top-line data from the placebo-controlled portion of this study is expected in the third quarter of 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. Top-line data from this placebo-controlled study is expected to closely follow the top-line results of the Kinect Study.

The Company anticipates an end of Phase II meeting for NBI-98854 in tardive dyskinesia to be held with the FDA in the fourth quarter of 2013.

Additionally, the Company has initiated a preclinical study to support the advancement of NBI-98854 into clinical trials for individuals suffering from Tourette's syndrome. Upon successful completion of this preclinical study, the Company anticipates entering Phase I 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 866-952-1908 (US) or 785-424-1827 (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 800-753-0348 (US) or 402-220-2672 (International) using the conference ID: NBIX. The call will be archived for one month.

Neurocrine Biosciences, Inc. is a biopharmaceutical company focused on neurological and endocrine-related diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, tardive dyskinesia, uterine fibroids, 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 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. 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)

	Three Months Ended March 31,	
	2013	2012
	(unaudited)	
Revenues:		
Sponsored research and development	$ -	$ 2,029
License fees	730	9,238
Total revenues	730	11,267
Operating expenses:		
Research and development	10,313	9,388
General and administrative	3,392	3,671
Total operating expenses	13,705	13,059
Loss from operations	(12,975)	(1,792)
Other income:		
Interest and other income	105	123
Gain on disposal of assets	795	783
Total other income	900	906
Net loss	$ (12,075)	$ (886)
Net loss per common share:		

Basic and Diluted	$ (0.18)	$ (0.01)
Shares used in the calculation of net loss per common share:		
Basic and Diluted	66,600	63,409

NEUROCRINE BIOSCIENCES, INC.
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2013	December 31, 2012
	(unaudited)	
Cash, cash equivalents and short-term marketable securities	$158,234	$ 173,013
Other current assets	2,161	16,251
Total current assets	160,395	189,264
Property and equipment, net	1,784	1,900
Long-term investments	17,410	480
Restricted cash	4,335	4,335
Total assets	$183,924	$195,979
Current liabilities	$13,878	$ 15,646
Long-term liabilities	25,093	25,961
Stockholders' equity	144,953	154,372
Total liabilities and stockholders' equity	$183,924	$195,979

SOURCE Neurocrine Biosciences, Inc.

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