Neurocrine Biosciences Reports Second Quarter 2015 Results

July 29, 2015

Patient recruitment nears completion for Kinect 3 Phase III Study
Chief Commercial Officer and Vice President of Medical Affairs join the Company
Elagolix twelve month endometriosis efficacy and safety data consistent with previously reported six month data

SAN DIEGO, July 29, 2015 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended June 30, 2015. For the second quarter of 2015, the Company reported a net loss of $24.0 million, or $0.28 loss per share, compared to a net loss of $13.4 million, or $0.18 loss per share, for the same period in 2014. For the six months ended June 30, 2015, the Company reported a net loss of $25.2 million, or $0.30 loss per share, as compared to net loss of $25.2 million, or $0.35 loss per share, for the first half of last year.

The Company's balance sheet at June 30, 2015 reflected total assets of $511.2 million, including cash, cash equivalents, investments and receivables of $501.5 million.

"During the first half of 2015 we have been focused on two primary tasks, executing on our Phase III Kinect clinical trials and beginning the commercial build for our VMAT2 inhibitor NBI-98854," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "To that end, we are nearing completion of randomization in Kinect 3 while Kinect 4 continues its strong enrollment. We made two key hires during the quarter: Eric Benevich, formerly of Avanir, joined as Chief Commercial Officer, and Bill Aurora, formerly of Merck, joined as Vice President of Medical Affairs. They have initiated both the commercial and medical outreach efforts that are crucial to the success of our VMAT2 franchise. Additionally, the twelve month dosing in the first elagolix endometriosis Phase III study has completed and we and our partner AbbVie are very encouraged that the efficacy and safety profile of elagolix at month twelve is consistent with the positive month six results shared earlier this year."

Research and development expenses were $18.7 million during the second quarter of 2015 compared to $10.2 million for the same period in 2014. For the six months ended June 30, 2015, research and development expenses were $35.3 million, compared to $18.7 million for the same period last year. This increase was primarily due to higher external clinical development expenses and associated internal costs related to NBI-98854, which initiated Phase III development in the second half of 2014 and preparations for a potential New Drug Application filing in 2016.

General and administrative expenses increased from $4.2 million for the second quarter of 2014 to $6.6 million for the second quarter of 2015. For the six months ended June 30, 2015, general and administrative expenses were $12.1 million, compared to $8.4 million for the first half of 2014. The increase in general and administrative expense is primarily due to higher personnel related costs, including a $1.5 million increase in year-to-date share-based compensation expense. Additionally, professional costs related to market research and pre-commercial activities contributed to the overall increase in general and administrative expenses.

Pipeline Highlights

VMAT2 Update

In 2014, the Company 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 as assessed by blinded central raters. The Kinect 3 study includes 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. Top-line efficacy data from the initial six weeks of placebo-controlled dosing is expected in the second half of 2015.

A separate one-year open-label safety study of NBI-98854, Kinect 4, has also been initiated to support the anticipated 2016 filing of a New Drug Application in tardive dyskinesia.

As announced previously, Neurocrine has also 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 are receiving a once-daily dose of NBI-98854 during a two-week treatment period to assess both the safety and tolerability of NBI-98854. Additionally, the Yale Global Tic Severity Scale and the Premonitory Urge for Tics Scale are being utilized during the study to assess the impact of NBI-98854 on the patients' Tourette symptoms. Data read out from the T-Force study is expected in the second half of 2015.

Elagolix Update

In early 2015, AbbVie announced positive top-line results from the first of two ongoing Phase III clinical trials, the Violet Petal Study, designed to evaluate the efficacy and safety of elagolix in premenopausal women with endometriosis. Results from the trial show that after six months of treatment, both doses of elagolix (150 mg once daily and 200 mg twice daily) met the study's co-primary endpoints ($p<0.001$) of reducing scores of non-menstrual pelvic pain and menstrual pain (or dysmenorrhea) associated with endometriosis at month three, as well as month six, as measured by the Daily Assessment of Endometriosis Pain scale. The observed safety profile of elagolix in the Violet Petal Study was consistent with observations from prior studies. Among the most common adverse events (AEs) were hot flush, headache, nausea and fatigue. While most AEs were similar across treatment groups some, such as hot flush and bone mineral density loss, were dose-dependent. AbbVie recently completed the six month extension of the initial elagolix Phase III endometriosis study and disclosed that the efficacy and safety at month twelve were consistent with the efficacy and safety findings seen at month six.

AbbVie is 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. Top-line efficacy data from this study is expected in the first quarter of 2016.

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. Patient recruitment has been completed and top-line data from this study is expected in the fall of 2015.

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 (858) 617-7600. A replay of the conference call will be available approximately one hour after the conclusion of the call by dialing 800-695-2185 (US) or 402-530-9028 (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 NBI-98854, a 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 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 include risks that clinical development activities may not be completed on time or at all; risks that clinical development activities may be delayed for regulatory or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that regulatory submissions may not occur or be submitted in a timely manner; risks that the Company's product candidates may not obtain regulatory approval or that the U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions regarding the Company's product candidates; risks that the Company's product candidates may be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks associated with the Company's dependence on AbbVie for elagolix development and commercialization and dependence on other third parties for development, manufacturing and marketing and sales activities; risks that the Company's research programs will not identify pre-clinical candidates for further development; risks that the Company will be unable to raise additional funding required to complete development of all of its product candidates; risk and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products; and other risks described in the Company's annual report on Form 10-K for the year ended December 31, 2014 and quarterly report on Form 10-Q for the quarter ended March 31, 2015. Neurocrine disclaims any 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,	
	2015	**2014**	**2015**	**2014**
Revenues:				
License fees	$ -	$ -	$ 19,769	$ -
Total revenues	-	-	19,769	-
Operating expenses:				
Research and development	18,719	10,161	35,294	18,733
General and administrative	6,603	4,200	12,085	8,353
Total operating expenses	25,322	14,361	47,379	27,086

Loss from operations	(25,322)	(14,361)	(27,610)	(27,086)
Other income:				
Gain (loss) on sale/disposal of assets	-	5	9	(5)
Deferred gain on real estate	829	805	1,659	1,609
Investment income, net	506	167	763	256
Other income, net	-	3	-	3
Total other income	1,335	980	2,431	1,863
Net loss	$ (23,987)	$(13,381)	$ (25,179)	$ (25,223)
Net loss per common share:				
Basic and diluted	$ (0.28)	$ (0.18)	$ (0.30)	$ (0.35)
Shares used in the calculation of net loss per common share:				
Basic and diluted	85,518	75,879	82,947	73,085

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

	June 30, 2015	December 31, 2014
Cash, cash equivalents and short-term marketable securities	$ 384,720	$ 193,809
Other current assets	4,696	4,394
Total current assets	389,416	198,203
Property and equipment, net	2,802	2,507
Long-term investments, available for sale	114,172	37,492
Restricted cash	4,815	4,831
Total assets	$ 511,205	$ 243,033
Current liabilities	$ 17,553	$ 15,664
Long-term liabilities	26,712	18,670
Stockholders' equity	466,940	208,699
Total liabilities and stockholders' equity	$ 511,205	$ 243,033

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neurocrine-biosciences-reports-second-quarter-2015-results-300120671.html

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