Neurocrine Biosciences Reports Year-End 2014 Results and Provides Investor Update for 2015

February 9, 2015

First Elagolix Phase III Study in Endometriosis is Successful
Second Elagolix Phase III Study in Endometriosis Scheduled for Top-Line Readout in 2015
Phase IIb Elagolix Data for Uterine Fibroids in Second Half of 2015
NBI-98854 Phase III Efficacy Data for Tardive Dyskinesia and Phase I Data in Tourette Due this Year
Results Expected in 2015 from NBI-77860 in Two Congenital Adrenal Hyperplasia Clinical Trials

SAN DIEGO, Feb. 9, 2015 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter and year ended December 31, 2014.

For the fourth quarter of 2014, the Company reported a net loss of $19.4 million, or $0.26 loss per share, compared to a net loss of $10.6 million, or $0.16 loss per share for the same period in 2013. For the year ended December 31, 2014, the Company reported a net loss of $60.5 million, or $0.81 loss per share, as compared to a net loss of $46.1 million, or $0.69 loss per share for 2013. The increase in net loss for the fourth quarter and full year result primarily from increased research and development expenses in connection with the Company's expanding clinical stage pipeline and higher share-based compensation expense as detailed below.

The Company's balance sheet at December 31, 2014 reflected total assets of $243.0 million, including cash, investments and receivables of $232.6 million compared with balances at December 31, 2013 of $154.7 million and $146.8 million, respectively.

"We began 2015 with positive data from our partner AbbVie in the initial Phase III study of elagolix in endometriosis and now look forward to seven additional clinical trial readouts for the balance of this year; 2015 will be the most data rich year in our history," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "Additionally, our investment in basic research has yielded a new compound for our clinical pipeline and we expect to file an Investigational New Drug application during the second quarter with Phase I clinical results later in the year."

Research and development expenses were $15.5 million during the fourth quarter of 2014, compared to $8.9 million for the same period in 2013. General and administrative expenses increased from $3.3 million for the fourth quarter of 2013 to $5.0 million for the fourth quarter of 2014. For the year ended December 31, 2014, research and development expenses were $46.4 million, compared to $39.2 million for all of 2013, while general and administrative expenses were $18.0 million during 2014, compared to $13.3 million for the prior year. The increase in year-to-date expenses is primarily due to an increase in personnel costs of $8.3 million, with share-based compensation expense representing $3.6 million of this increase. The Company increased its research and development headcount during 2014 in response to its clinical pipeline expansion. Additionally, higher external clinical development costs and early research costs resulted in a net increase of approximately $1.7 million from 2013 levels.

2015 Financial Guidance

The Company expects to have a gross cash burn, prior to any revenue, of approximately $80 million to $85 million in 2015. The increase in cash burn from 2014 is primarily due to the expansion and progression of the clinical pipeline. Expenses for 2015 should approximate $106 million to $111 million. The anticipated increase in expenses over 2014 levels also includes an estimated $15 million increase in share-based compensation expense, partially due to anticipated partial vesting of certain performance-based restricted stock units.

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 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 is also being initiated to support the anticipated 2016 filing of a New

Drug Application in tardive dyskinesia.

Neurocrine 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 are receiving 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 are being utilized during the study to assess the impact of NBI-98854 on the patients' Tourette symptoms. Data readout from the T-Force study is expected in the second half of 2015.

Elagolix Update

AbbVie recently 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 (NMPP) 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 (BMD) loss, were dose-dependent.

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. Top-line efficacy data from this study is expected in late 2015.

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. Data from this study is expected in 2015.

Corticotropin Releasing Factor (Congenital Adrenal Hyperplasia) Update

The Company recently announced the completion of a pilot clinical trial of NBI-77860 against placebo in adult females with refractory classic congenital adrenal hyperplasia (CAH). This eight person single dose exploratory study showed that NBI-77860 was effective in reducing the key biomarkers of adrenocorticotropic hormone (ACTH) and 17-hydroxyprogesterone androgen (17-OHP). A full description of the study results and related data will be presented at the Endocrine Society's 97th Annual Meeting on March 5, 2015 in San Diego.

Neurocrine has initiated a second clinical trial assessing three doses of NBI-77860 in an open-label, sequential cohort, single ascending dose pharmacokinetic/pharmacodynamic study. Fifteen adolescent females with classic CAH will be split into three cohorts and each will receive one dose of NBI-77860 once a day. Biomarker measurements include ACTH, 17-OHP, androgen and cortisol levels collected the morning after dosing. Data from this study is expected later in 2015.

Conference Call and Webcast Today at 5:00 PM 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 (858) 617-7600. 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. 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 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 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, 2013 and quarterly reports on Form 10-Q for the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014. 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 December 31,		Year Ended December 31,	
	2014	**2013**	**2014**	**2013**
Revenues:				
Milestones and license fees	$ -	$ 730	$ -	$ 2,919
Total revenues	-	730	-	2,919
Operating expenses:				
Research and development	15,498	8,918	46,425	39,248
General and administrative	4,970	3,342	17,986	13,349
Total operating expenses	20,468	12,260	64,411	52,597
Loss from operations	(20,468)	(11,530)	(64,411)	(49,678)
Other income:				
(Loss) gain on sale/disposal of assets	-	(1)	(4)	37
Deferred gain on real estate	812	789	3,226	3,133
Investment income, net	197	85	629	402
Other income, net	15	15	18	16
Total other income	1,024	888	3,869	3,588
Net loss	$ (19,444)	$ (10,642)	$ (60,542)	$ (46,090)
Net loss per common share:				
Basic and Diluted	$ (0.26)	$ (0.16)	$ (0.81)	$ (0.69)
Shares used in the calculation of net (loss) income per common share:				
Basic and Diluted	76,139	67,346	74,577	66,989

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

	December 31, 2014	December 31, 2013
Cash, cash equivalents and short-term marketable securities	$ 193,809	$ 145,739
Other current assets	4,394	2,723
Total current assets	198,203	148,462
Property and equipment, net	2,507	1,771
Long-term investments	37,492	-
Restricted cash	4,831	4,443

Total assets	$ 243,033	$ 154,676
Current liabilities	$ 15,664	$ 11,699
Long-term liabilities	18,670	22,567
Stockholders' equity	208,699	120,410
Total liabilities and stockholders' equity	$ 243,033	$ 154,676

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neurocrine-biosciences-reports-year-end-2014-results-and-provides-investor-update-for-2015-300032978.html

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