Neurocrine Biosciences Reports Year-End 2015 Results and Provides Investor Update for 2016

February 11, 2016

Valbenazine New Drug Application to be filed for Tardive Dyskinesia this Year
Second Elagolix Phase III Study in Endometriosis is Successful
Two Phase III Studies of Elagolix in Uterine Fibroids Underway
Two Phase II Studies of Valbenazine in Tourette Syndrome Expected to Readout Near Year-End
Two Clinical Trial Readouts Expected in 2016 from Essential Tremor Drug Candidate NBI-640756

SAN DIEGO, Feb. 11, 2016 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter and year ended December 31, 2015.

For the fourth quarter of 2015, the Company reported a net loss of $29.3 million, or $0.34 loss per share, compared to a net loss of $19.4 million, or $0.26 loss per share for the same period in 2014. For the year ended December 31, 2015, the Company reported a net loss of $88.9 million, or $1.05 loss per share, as compared to a net loss of $60.5 million, or $0.81 loss per share for 2014. The increase in net loss for the fourth quarter and full year results primarily from increased research and development expenses in connection with the Company's advancing clinical stage pipeline, valbenazine pre-commercialization activities for tardive dyskinesia and higher share-based compensation expense as detailed below.

The Company's balance sheet at December 31, 2015 reflected total assets of $474.8 million, including cash, investments and receivables of $464.3 million compared with balances at December 31, 2014 of $243.0 million and $232.6 million, respectively.

"We begin 2016 with positive top-line data from our partner AbbVie in the second Phase III study of elagolix in endometriosis coupled with the start of two Phase III studies of elagolix in uterine fibroids," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "Recently we reported a highly positive Phase III study of valbenazine in tardive dyskinesia and now look forward to filing our valbenazine NDA for tardive dyskinesia with the FDA this year. We have also initiated two Phase II studies of valbenazine in Tourette syndrome with data on these expected around the end of the year. Additionally, we have NBI-640756, our drug candidate for essential tremor, in the clinic and we look to add yet another new compound to our clinical pipeline later this year."

Research and development expenses were $21.8 million during the fourth quarter of 2015, compared to $15.5 million for the same period in 2014. For the year ended December 31, 2015, research and development expenses were $81.5 million, compared to $46.4 million for all of 2014. The increase in research and development expense was 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, as well as preparations for a potential New Drug Application filing in 2016. Additionally, year-to-date share-based compensation expense increased by $7.9 million from 2014 levels primarily due to performance-based restricted stock units.

General and administrative expenses increased from $5.0 million for the fourth quarter of 2014 to $8.9 million for the fourth quarter of 2015. For the year ended December 31, 2015 general and administrative expenses were $32.5 million, compared to $18.0 million for the prior year. The increase in general and administrative expense is primarily due to higher personnel related costs, including a $10.1 million increase in year-to-date share-based compensation expense primarily due to performance-based restricted stock units. Additionally, professional costs related to market research and pre-commercialization activities contributed to the overall increase in general and administrative expenses.

2016 Financial Guidance

The Company expects to have a cash burn of approximately $135 million to $145 million in 2016. The increase in cash burn from 2015 is primarily due to preparing for commercialization of valbenazine in tardive dyskinesia coupled with expansion and progression of the clinical pipeline. Revenues for 2016 are expected to be approximately $15 million. Expenses for 2016 should approximate $185 million to $195 million. The anticipated expenses include an estimated $30 million for share-based compensation expense.

Pipeline Highlights

Valbenazine Update

During the fourth quarter of 2015, the Company announced positive top-line results from the Kinect 3 study, a Phase III trial that included moderate to severe tardive dyskinesia in patients with underlying schizophrenia, schizoaffective disorder, bipolar or major depressive disorder. The Kinect 3 study randomized 234 subjects to either placebo, once-daily 40mg of NBI-98854 (valbenazine), or once-daily 80mg of valbenazine for six weeks of placebo-controlled dosing followed by an extension of active dosing through Week 48. The primary efficacy endpoint was the change-from-baseline in the Abnormal Involuntary Movement Scale (AIMS) at Week 6 in the 80mg once-daily dosing group compared to placebo as assessed by central blinded video raters. The AIMS ratings at Week 6 for the 80mg once-daily valbenazine intention-to-treat (ITT) population was reduced 3.1 points (Least-Squares Mean) more than placebo ($p<0.0001$). During the six-week placebo-controlled treatment period valbenazine was generally well tolerated. The frequency of adverse events was similar among all treatment groups and treatment emergent adverse effects were consistent with those of prior studies.

In addition to the ongoing safety assessment of Kinect 3, the Company is also conducting a separate one-year open-label safety study of valbenazine, Kinect 4, to support the anticipated 2016 filing of a New Drug Application of valbenazine in tardive dyskinesia. As announced previously, Neurocrine has received Breakthrough Therapy Designation from the FDA for valbenazine in the treatment of tardive dyskinesia.

The Company is also exploring valbenazine in Tourette syndrome. The initial Tourette's clinical trial, the T-Force study, was an open-label, multi-dose, two-week evaluation of 28 subjects with Tourette syndrome. Children and adolescents enrolled in the trial are receiving a once-daily dose of

valbenazine during a two-week treatment period to assess both the safety and tolerability of valbenazine. Valbenazine was generally safe and well tolerated. The Yale Global Tic Severity Scale was also assessed and after two weeks of treatment showed a mean reduction of 31% from baseline scores, with over half of the subjects considered clinical responders.

The Company recently announced the initiation of two Phase II Tourette syndrome studies evaluating valbenazine in adults and pediatrics, the T-Forward study and T-Force GREEN study, respectively.

The T-Forward study is a randomized, double-blind, placebo-controlled, multi-dose, parallel group, study of up to 90 adults. Subjects will receive once-daily dosing of valbenazine during an eight-week treatment period to assess the safety, tolerability and efficacy of valbenazine in adult Tourette patients. The primary endpoint of this study is a change from baseline of placebo vs. active scores utilizing the Yale Global Tic Severity Scale at the end of Week 8.

The T-Force GREEN study is a randomized, double-blind, placebo-controlled, multi-dose, parallel group, study of up to 90 children and adolescents. Subjects will receive once-daily dosing of valbenazine during a six-week treatment period to assess the safety, tolerability and efficacy of valbenazine in pediatric Tourette patients. The primary endpoint of this study is the change from baseline of the Yale Global Tic Severity Scale between placebo and active treatment groups at the end of week six.

Data from both of these Tourette studies is expected around year-end 2016.

Elagolix Update

AbbVie recently announced positive top-line results from the second of two Phase III clinical trials, the Solstice Study, a multinational study designed to evaluate the efficacy and safety of elagolix in 815 premenopausal women with endometriosis. The top-line results from this trial were consistent with those of the initial Phase III clinical trial, the Violet Petal Study, where 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 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 Solstice study was consistent with observations from prior studies. Among the most common adverse events (AEs) were hot flush, headache, and nausea. While most AEs were similar across treatment groups some, such as hot flush and bone mineral density loss, were dose-dependent. AbbVie is targeting a 2017 New Drug Application filing with the FDA for elagolix in endometriosis.

In early 2016, AbbVie announced the initiation of the Phase III uterine fibroids program consisting of two replicate randomized, parallel, double-blind, placebo-controlled clinical trials evaluating elagolix alone or in combination with add-back therapy in women with heavy uterine bleeding associated with uterine fibroids. The studies are expected to enroll approximately 400 subjects each for an initial six-month placebo-controlled dosing period. At the end of the six-months of placebo-controlled evaluation, subjects are eligible to enter an additional six-month safety extension study. The primary efficacy endpoint of the study is an assessment of the change in menstrual blood loss utilizing the alkaline hematin method comparing baseline to month six. Additional secondary efficacy endpoints will be evaluated including assessing the change in fibroid volume and hemoglobin. Bone mineral density will be assessed via DXA scan at baseline, the conclusion of dosing, and six months post-dosing.

In September 2015, AbbVie announced positive top-line results from a Phase IIb clinical trial in women with heavy menstrual bleeding associated with uterine fibroids. The trial evaluated the safety and efficacy of elagolix alone or in combination with add-back therapy compared to placebo. Preliminary results showed that all of the elagolix treatment arms, with and without add-back therapy, reduced heavy menstrual bleeding as compared to placebo ($p<0.001$). Among the most common adverse AEs were hot flush, headache, nausea, and vomiting. Some AEs such as hot flush were more frequent in the elagolix only treatment arms as compared to the placebo and elagolix with add-back therapy treatment arms. Bone mineral density loss associated with elagolix alone was attenuated when elagolix was co-administered with add-back therapy.

Essential Tremor Program (NBI-640756) Update

NBI-640756 for patients with essential tremor was discovered in the Neurocrine laboratories. The Company has initiated a single site, randomized, double-blind, placebo-controlled, sequential dose-escalation, pharmacokinetic study assessing the safety and tolerability of a single dose of NBI-640756 in up to 32 healthy volunteers. The study is being conducted in multiple sequential cohorts of eight subjects per cohort. Top-line data from this Phase I study is expected in the first-half of 2016.

Conference Call and Webcast Today at 4:30 PM Eastern Time

Neurocrine will hold a live conference call and webcast today at 4:30 p.m. Eastern Time (1:30 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 (858) 617-7600. A replay of the conference call will be available approximately one hour after the conclusion of the call by dialing 800-677-6124 (US) or 402-220-0664 (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 valbenazine, 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 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 associated with the Company's

dependence on AbbVie for the development and commercialization of elagolix; 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 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 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 reports on Form 10-Q for the quarters ended March 31, 2015, June 30, 2015 and September 30, 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 December 31,		Year Ended December 31,	
	2015	**2014**	**2015**	**2014**
Revenues:				
Milestones and license fees	$ -	$ -	$ 19,769	$ -
Total revenues	-	-	19,769	-
Operating expenses:				
Research and development	21,809	15,498	81,491	46,425
General and administrative	8,939	4,970	32,480	17,986
Total operating expenses	30,748	20,468	113,971	64,411
Loss from operations	(30,748)	(20,468)	(94,202)	(64,411)
Other income:				
(Loss) gain on sale/disposal of assets	-	-	9	(4)
Deferred gain on real estate	838	812	3,325	3,226
Investment income, net	584	197	1,928	629
Other income, net	11	15	11	18
Total other income	1,433	1,024	5,273	3,869
Net loss	$ (29,315)	$ (19,444)	$ (88,929)	$ (60,452)
Net loss per common share:				
Basic and Diluted	$ (0.34)	$ (0.26)	$ (1.05)	$ (0.81)

Shares used in the calculation of net (loss) income per common share:				
Basic and Diluted	86,184	76,139	84,496	74,577

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

	December 31, 2015	December 31, 2014
Cash, cash equivalents and short-term marketable securities	$ 379,191	$ 193,809
Other current assets	4,883	4,394
Total current assets	384,074	198,203
Property and equipment, net	3,432	2,507
Long-term investments	82,488	37,492
Restricted cash	4,791	4,831
Total assets	$ 474,785	$ 243,033
Current liabilities	$ 25,715	$ 15,664
Long-term liabilities	24,616	18,670
Stockholders' equity	424,454	208,699
Total liabilities and stockholders' equity	$ 474,785	$ 243,033

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neurocrine-biosciences-reports-year-end-2015-results-and-provides-investor-update-for-2016-300219066.html

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