Neurocrine Biosciences Reports Third Quarter 2015 Results

October 29, 2015

NBI-98854 Positive in Phase III Study in Tardive Dyskinesia, NDA filing in 2016
Elagolix Phase IIb Study in Uterine Fibroids is Positive, Moving into Phase III Development

SAN DIEGO, Oct. 29, 2015 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended September 30, 2015. For the third quarter of 2015, the Company reported a net loss of $34.4 million, or $0.40 loss per share, compared to a net loss of $15.9 million, or $0.21 loss per share, for the same period in 2014. For the nine months ended September 30, 2015, the Company reported a net loss of $59.6 million, or $0.71 loss per share, as compared to net loss of $41.1 million, or $0.56 loss per share, for the first nine months of last year.

The Company's balance sheet at September 30, 2015 reflected total assets of $492.4 million, including cash, cash equivalents, investments and receivables of $481.7 million.

"We have made significant progress over the past three months across our clinical programs, including the successful Kinect 3 Phase III study of NBI-98854 in tardive dyskinesia, our partner AbbVie reported positive results in the Phase IIb study of elagolix in uterine fibroids and is moving forward into Phase III development for uterine fibroids, and also the recent initiation of our Phase II study of NBI-98854 in adults with Tourette syndrome," said Kevin Gorman, President and Chief Executive Officer of Neurocrine Biosciences. "We look forward to the readout from our Phase Ib study of NBI-98854 in children and adolescents with Tourette's in December of this year."

Research and development expenses were $24.4 million during the third quarter of 2015 compared to $12.2 million for the same period in 2014. For the nine months ended September 30, 2015, research and development expenses were $59.7 million, compared to $30.9 million for the same period last year. This increase 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 $6.6 million from 2014 levels primarily due to performance-based restricted stock units.

General and administrative expenses increased from $4.7 million for the third quarter of 2014 to $11.5 million for the third quarter of 2015. For the nine months ended September 30, 2015, general and administrative expenses were $23.5 million, compared to $13.0 million for the first nine months of 2014. The increase in general and administrative expense is primarily due to higher personnel related costs, including a $7.7 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.

Updated 2015 Financial Guidance

The Company expects to end 2015 with in excess of $450 million in cash, investments and receivables. The gross cash burn from operations, prior to any revenues, remains unchanged at approximately $85 million for 2015. Total expenses for 2015 are expected to be approximately $110 to $115 million. The previous financial guidance for expenses during 2015 ranged from of $106 to $111 million. Based on the positive results of the Kinect 3 study of NBI-98854 in tardive dyskinesia, the Company is accelerating certain activities originally planned for 2016 into the fourth quarter of 2015.

Pipeline Highlights

VMAT2 Update

Earlier this month, the Company announced positive top-line results from the Kinect 3 study, a Phase III trial that included moderate to severe tardive dyskinesia 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, or once daily 80mg of NBI-98854 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 NBI-98854 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 NBI-98854 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 NBI-98854, Kinect 4, to support the anticipated 2016 filing of a New Drug Application in tardive dyskinesia.

As announced previously, Neurocrine has received Breakthrough Therapy Designation from the FDA for NBI-98854 in the treatment of tardive dyskinesia.

The Company is also exploring NBI-98854 in Tourette syndrome. The initial Tourette's clinical trial, the T-Force study, is an open-label, multi-dose, two-week evaluation of up to 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 from the T-Force study is expected later in 2015.

The Company recently announced the initiation of a second Tourette syndrome study evaluating NBI-98854 in adults, the T-Forward Study. This 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 NBI-98854 during an eight-week treatment period to assess the safety, tolerability and efficacy of NBI-98854 in 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. Data from this study is expected later in 2016.

Elagolix Update

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. Reduction in bone mineral density associated with elagolix alone was attenuated when elagolix was co-administered with add-back therapy. The elagolix uterine fibroids Phase III program is targeted to begin the first quarter of 2016 and will include two replicate, pivotal, six-month efficacy and safety studies followed by a six-month safety and efficacy extension study.

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.

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 866-952-1907 (US) or 785-424-1826 (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 800-839-5127 (US) or 402-220-2692 (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 and June 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 September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Revenues:				
License fees	$ -	$ -	$ 19,769	$ -
Total revenues	-	-	19,769	-
Operating expenses:				
Research and development	24,388	12,194	59,682	30,927
General and administrative	11,456	4,663	23,541	13,016
Total operating expenses	35,844	16,857	83,223	43,943
Loss from operations	(35,844)	(16,857)	(63,454)	(43,943)
Other income:				
Gain (loss) on sale/disposal of assets	-	1	9	(4)
Deferred gain on real estate	828	805	2,487	2,414
Investment income, net	581	176	1,344	432
Other income, net	-	-	-	3
Total other income	1,409	982	3,840	2,845

Net loss	$ (34,435)	$(15,875)	$ (59,614)	$ (41,098)
Net loss per common share:				
Basic and diluted	$ (0.40)	$ (0.21)	$ (0.71)	$ (0.56)
Shares used in the calculation of net loss per common share:				
Basic and diluted	85,856	75,948	83,927	74,050

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

	September 30, 2015	December 31, 2014
Cash, cash equivalents and short-term marketable securities	$ 376,845	$ 193,809
Other current assets	5,940	4,394
Total current assets	382,785	198,203
Property and equipment, net	2,874	2,507
Long-term investments, available for sale	101,986	37,492
Restricted cash	4,791	4,831
Total assets	$ 492,436	$ 243,033
Current liabilities	$ 19,822	$ 15,664
Long-term liabilities	25,671	18,670
Stockholders' equity	446,943	208,699
Total liabilities and stockholders' equity	$ 492,436	$ 243,033

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neurocrine-biosciences-reports-third-

quarter-2015-results-300168966.html

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