Neurocrine Biosciences Reports Second Quarter 2016 Results

August 3, 2016

-Valbenazine New Drug Application for Tardive Dyskinesia to be Submitted in 2016-
- Valbenazine Presentations at Three Major Scientific Conferences during Second Quarter-
-Long-Term Tourette Syndrome Study Initiated-
-NBI-640756 for Essential Tremor Moves into Second Phase I Study-

SAN DIEGO, Aug. 3, 2016 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended June 30, 2016. For the second quarter of 2016, the Company reported a net loss of $40.3 million, or $0.46 loss per share, compared to a net loss of $24.0 million, or $0.28 loss per share, for the same period in 2015. For the six months ended June 30, 2016, the Company reported a net loss of $59.5 million, or $0.69 loss per share, as compared to a net loss of $25.2 million, or $0.30 loss per share, for the first half of last year.

The Company's balance sheet at June 30, 2016 reflected total assets of $429.8 million, including cash, cash equivalents, investments and receivables of $416.5 million.

"During the first half of 2016 Neurocrine has been acutely focused on two fronts: preparing our NDA for valbenazine in tardive dyskinesia and pre-commercialization activities related to readying valbenazine for commercial launch," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "Our R&D team has been carefully compiling the extensive data from our 20 clinical trials of valbenazine along with the preclinical and drug manufacturing data into an NDA that we anticipate will be submitted to the FDA soon. We have fully deployed our medical affairs team and continue to build the capabilities to introduce valbenazine to patients and a treatment community in need of new medicines for a serious disorder."

Research and development expenses were $26.9 million during the second quarter of 2016 compared to $18.7 million for the same period in 2015. For the six months ended June 30, 2016, research and development expenses were $50.8 million, compared to $35.3 million for the same period last year. This increase was primarily due to higher external clinical development expenses and associated internal costs related to the Company's VMAT2 inhibitor, valbenazine, which is being evaluated in both tardive dyskinesia and Tourette syndrome. Additionally, expenses related to the Company's preparation for the submission of a New Drug Application for valbenazine in tardive dyskinesia accounted for a significant portion of the increase in expenses for both quarter over quarter and year over year.

General and administrative expenses increased from $6.6 million for the second quarter of 2015 to $15.0 million for the second quarter of 2016. For the six months ended June 30, 2016, general and administrative expenses were $26.9 million, compared to $12.1 million for the first half of 2015. The increase in general and administrative expense is primarily due to pre-commercialization activities for valbenazine. Personnel related costs increased by $4.1 million quarter over quarter and $8.1 year over year primarily due to the expansion of sales and marketing and medical affairs personnel. Approximately 50% of the increase in personnel related costs during each of the periods is due to an increase in share-based compensation costs. Additionally, professional costs related to market research and other pre-commercial activities contributed to the overall increase in general and administrative expenses.

Pipeline Highlights

Valbenazine Update

During the fourth quarter of 2015, the Company announced positive efficacy 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 who underwent six weeks of placebo controlled assessment. Subsequent to the initial six weeks of treatment, subjects were eligible to continue in the Kinect 3 study for up to 42 weeks of additional valbenazine treatment. The last subject is anticipated to complete dosing in August 2016.

In addition to the long-term extension phase of Kinect 3, during the first quarter of 2016 the Company completed enrollment in a separate one-year open-label safety study of valbenazine, Kinect 4, to support the anticipated 2016 submission of a New Drug Application of valbenazine in tardive dyskinesia.

The Company also recently initiated a valbenazine roll-over study for those patients who complete the one year of dosing in either the Kinect 3 or Kinect 4 studies. This roll-over study is designed to permit open-label access to valbenazine for up to an additional 72 weeks of treatment.

During the second quarter of 2016, the Company presented eight valbenazine abstracts at three major medical meetings. Valbenazine data from the Kinect clinical trials were presented at podium and plenary sessions at the American Academy of Neurology Annual Meeting in April. In addition, four valbenazine scientific abstracts were presented at the American Psychiatric Association Annual Meeting in May. Data from Kinect 3 was also shared at the 20th International Congress of Parkinson's Disease and Movement Disorders in Berlin during the month of June.

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 Company has two ongoing placebo-controlled 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 6.

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

Additionally, the Company has recently launched an open-label, fixed-dose study of valbenazine in up to 180 subjects with Tourette syndrome. This study is designed to enroll up to 90 children and adolescents and up to 90 adults who have completed either of the two placebo-controlled Tourette clinical trials: T-Force GREEN or T-Forward. This Phase II study will assess the long-term safety and tolerability of valbenazine in children and adults with Tourette's.

Elagolix Update

During the first quarter of 2016, AbbVie 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. The Company expects the initial top line efficacy data from the uterine fibroid Phase III program in 2017.

Essential Tremor Program (NBI-640756) Update

NBI-640756 for patients with essential tremor was discovered in the Neurocrine laboratories. The Company has successfully completed an initial Phase I 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.

Based on the results of this initial study, the Company has initiated a second Phase I, single site, randomized, double-blind, placebo-controlled, multiple-dose, sequential dose-escalation study to evaluate the safety, tolerability and pharmacokinetics of NBI-640756 in up to 30 healthy volunteers over a week of continuous dosing. The study is being conducted in multiple sequential cohorts of ten subjects per cohort; data from this second Phase I study is expected later in 2016. The data from this study, in conjunction with the single dose Phase I study and preclinical studies, will be evaluated and utilized in the design of the anticipated Phase II program for NBI-640756.

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 888-632-3384 (US) or 785-424-1675 (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 800-839-1246 (US) or 402-220-0464 (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, 2015 and quarterly report on Form 10-Q for the quarter ended March 31, 2016. 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,	
	2016	**2015**	**2016**	**2015**
Revenues:				
License fees and milestones	$ -	$ -	$ 15,000	$ 19,769
Total revenues	-	-	15,000	19,769
Operating expenses:				
Research and development	26,863	18,719	50,766	35,294
General and administrative	14,965	6,603	26,919	12,085
Total operating expenses	41,828	25,322	77,685	47,379

Loss from operations	(41,828)	(25,322)	(62,685)	(27,610)
Other income:				
Gain on sale/disposal of assets	14	-	17	9
Deferred gain on real estate	854	829	1,707	1,659
Investment income, net	680	506	1,417	763
Total other income	1,548	1,335	3,141	2,431
Net loss	$ (40,280)	$ (23,987)	$(59,544)	$ (25,179)
Net loss per common share:				
Basic and diluted	$ (0.46)	$ (0.28)	$ (0.69)	$ (0.30)
Shares used in the calculation of net loss per common share:				
Basic and diluted	86,694	85,518	86,595	82,947

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

	June 30, 2016	December 31, 2015
	(unaudited)	
Cash, cash equivalents and short-term marketable securities	$387,398	$ 379,191
Other current assets	4,568	4,883
Total current assets	391,966	384,074
Property and equipment, net	5,811	3,432
Long-term investments	27,178	82,488
Restricted cash	4,883	4,791
Total assets	$429,838	$474,785
Current liabilities	$26,899	$ 25,715
Long-term liabilities	21,901	24,616

Stockholders' equity	381,038	424,454
Total liabilities and stockholders' equity	$429,838	$474,785

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neurocrine-biosciences-reports-second-quarter-2016-results-300308595.html

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