Neurocrine Biosciences Reports First Quarter 2016 Results

May 5, 2016

-Valbenazine New Drug Application for Tardive Dyskinesia to be Filed in 2016-
-Kinect 4 Fully Enrolled, Valbenazine Presentations at Major Scientific Conferences in Second Quarter-
-AbbVie Reports Positive Top-Line Efficacy from Second Elagolix Endometriosis Phase III Study, Initiates Two Phase III Studies of Elagolix in Uterine Fibroids-

SAN DIEGO, May 5, 2016 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended March 31, 2016. For the first quarter of 2016, the Company reported a net loss of $19.3 million, or $0.22 loss per share, compared to a net loss of $1.2 million, or $0.01 loss per share, for the same period in 2015.

The Company's balance sheet at March 31, 2016 reflected cash, cash equivalents, investments and receivables of $448.6 million compared to $464.3 million at December 31, 2015.

"2015 was a very successful year for Neurocrine and we have carried this momentum into the first quarter of 2016 beginning with positive top-line data from the second Phase III study of elagolix in endometriosis, the initiation of two Phase III studies of elagolix in uterine fibroids, the start of our Phase II T-Force GREEN study of valbenazine in children and adolescents with Tourette syndrome, as well as the acceptance of seven valbenazine abstracts at the American Academy of Neurology and American Psychiatric Association Annual Meetings" said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "Our focus for the coming months is to continue to execute across all aspects of our business; advancing compounds from research into the clinic, executing on clinical trials, filing the valbenazine NDA, and interacting with providers and payers as we prepare for the commercial launch of valbenazine for tardive dyskinesia upon FDA approval."

The $15.0 million of revenue for the first quarter of 2016 represents a milestone payment from AbbVie related to the commencement of Phase III studies of elagolix in uterine fibroids. The $19.8 million of revenue for the first quarter of 2015 represents recognized revenue in the form of license fees from the NBI-98854 (valbenazine) collaboration and license agreement with Mitsubishi Tanabe.

Research and development expenses increased to $23.9 million during the first quarter of 2016 from $16.6 million during the same period in 2015. 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 of the New Drug Application for valbenazine in tardive dyskinesia accounted for a portion of the increase in expenses quarter over quarter.

General and administrative expenses increased from $5.5 million in the first quarter of 2015 to $12.0 million for the first quarter of 2016, primarily due to pre-commercialization activities for valbenazine. Personnel related costs increased by $3.9 million quarter over quarter primarily due to the expansion of sales and marketing and medical affairs personnel. This increase in personnel related costs includes a $2.4 million increase in share-based compensation expense. Additionally, a significant increase in other pre-commercialization activities contributed to the overall growth 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 an additional 42 week open-label safety assessment. The open-label safety evaluation is anticipated to complete dosing in mid-2016.

In addition to the ongoing safety assessment 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 filing 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.

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 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 6.

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

The Company has submitted and had accepted seven valbenazine abstracts at two major medical conferences during the second quarter. Valbenazine data from all three 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 submitted and accepted for the American Psychiatric Association Annual Meeting in May.

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.

Essential Tremor Program (NBI-640756) Update

NBI-640756 for patients with essential tremor was discovered in the Neurocrine laboratories. The Company has completed dosing in 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 was conducted in multiple sequential cohorts of eight subjects per cohort. Data from this initial Phase I study is expected in the second 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 877-876-9174 (US) or 785-424-1669 (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 800-695-2533 (US) or 402-530-9029 (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. 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)

	Three Months Ended March 31,	
	2016	2015
	(unaudited)	
Revenues:		
License fees and milestones	$ 15,000	$ 19,769
Total revenues	15,000	19,769
Operating expenses:		
Research and development	23,903	16,575
General and administrative	11,954	5,482
Total operating expenses	35,857	22,057
Loss from operations	(20,857)	(2,288)
Other income:		
Interest and other income	737	257
Gain on sale of assets	856	839
Total other income	1,593	1,096
Net loss	$ (19,264)	$ (1,192)
Net loss per common share:		

Basic and Diluted	$ (0.22)	$ (0.01)
Shares used in the calculation of net loss per common share:		
Basic and Diluted	86,497	80,349

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

	March 31, 2016	December 31, 2015
	(unaudited)	
Cash, cash equivalents and short-term marketable securities	$381,524	$ 379,191
Other current assets	19,460	4,883
Total current assets	400,984	384,074
Property and equipment, net	3,897	3,432
Long-term investments	49,460	82,488
Restricted cash	4,991	4,791
Total assets	$459,332	$474,785
Current liabilities	$23,276	$ 25,715
Long-term liabilities	23,097	24,616
Stockholders' equity	412,959	424,454
Total liabilities and stockholders' equity	$459,332	$474,785

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neurocrine-biosciences-reports-first-quarter-2016-results-300263898.html

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