Neurocrine Biosciences Reports Second Quarter 2014 Results

August 6, 2014

SUCCESSFUL END-OF-PHASE II MEETING FOR NBI-98854 IN TARDIVE DYSKINESIA
TOURETTE SYNDROME IND FOR NBI-98854 TO BE FILED THIS MONTH

SAN DIEGO, Aug. 6, 2014 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended June 30, 2014. For the second quarter of 2014, the Company reported a net loss of $13.4 million, or $0.18 loss per share, compared to a net loss of $12.2 million, or $0.18 loss per share, for the same period in 2013. For the six months ended June 30, 2014, the Company reported a net loss of $25.2 million, or $0.35 loss per share, as compared to net loss of $24.3 million, or $0.36 loss per share, for the first half of last year.

The Company's balance sheet at June 30, 2014 reflected total assets of $269.5 million, including cash, cash equivalents, investments and receivables of $261.5 million.

"We are very pleased with our recent interactions with the FDA concerning our VMAT2 inhibitor NBI-98854 and the path forward to an NDA filing in tardive dyskinesia," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "Based on the results of the End-of-Phase II meeting, we will conduct a single placebo-controlled Phase III trial (Kinect 3). We look forward to initiating the Kinect 3 pivotal trial later this year."

Research and development expenses were $10.2 million during the second quarter of 2014 compared to $10.5 million for the same period in 2013. For the six months ended June 30, 2014, research and development expenses were $18.7 million, compared to $20.8 million for the same period last year. This decrease was due to lower external clinical development expense related to the Company's VMAT2 inhibitor, NBI-98854, which substantially completed Phase II development in late 2013 and is currently in preparation for Phase III development. This decrease was offset by higher research and development personnel costs primarily related to higher share-based compensation expense.

General and administrative expenses increased from $3.4 million for the second quarter of 2013 to $4.2 million for the second quarter of 2014. For the six months ended June 30, 2014 general and administrative expenses were $8.4 million, compared to $6.8 million for the first half of 2013. The increase in general and administrative expense is primarily due to higher share-based compensation expense.

Pipeline Highlights

VMAT2 Update

The Company recently held an End-of-Phase II meeting with the FDA for its VMAT2 inhibitor, NBI-98854. The FDA reviewed the current data package and clinical development plan for NBI-98854 and commented on the overall proposal for Phase III development to support the registration of NBI-98854 in the United States as a treatment for tardive dyskinesia. Based on the results of this meeting and the related minutes, the Company will conduct a single placebo-controlled Phase III study of NBI-98854, the Kinect 3 study. The Kinect 3 study, along with the previous efficacy studies of NBI-98854, will complete the placebo-controlled clinical efficacy evaluation of NBI-98854 in tardive dyskinesia. The primary endpoint in the Kinect 3 study will be the mean change from baseline in the Abnormal Involuntary Movement Scale (AIMS) as assessed by blinded central raters. The Kinect 3 study will include approximately 240 subjects randomized to either placebo, once daily 40mg of NBI-98854 or once daily 80mg of NBI-98854 for 6 weeks of placebo-controlled dosing followed by an extension of active dosing through Week 48. The Company also intends to conduct a separate one-year open-label safety study of NBI-98854 to support the anticipated 2016 filing of a New Drug Application in tardive dyskinesia.

The Company is also expecting to submit an Investigational New Drug application for NBI-98854 in Tourette syndrome later this month and plans to commence the clinical program in Tourette syndrome patients this year.

Elagolix Update

AbbVie is currently conducting the Violet Petal Study, a Phase III study of elagolix for endometriosis. The study is a 24-week, multinational, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of elagolix in 875 women, age 18 to 49, with moderate to severe endometriosis-associated pain. Approximately 160 sites in the United States, Puerto Rico and Canada are conducting this study which completed patient recruitment and randomization during the second quarter.

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.

Elagolix is also being studied for utilization in uterine fibroids. AbbVie is conducting a Phase IIb clinical trial evaluating the change in uterine blood loss of 520 women, age 18-51, with heavy uterine bleeding due to uterine fibroids.

Conference Call and Webcast Tomorrow at 8:00AM Eastern Time

Neurocrine will hold a live conference call and webcast tomorrow at 8:00 a.m. Eastern Time (5:00 a.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 ir@neurocrine.com. A replay of the conference call will be available approximately one hour after the conclusion of the call by dialing 800-839-2459 (US) or 402-220-7218 (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 R&D pipeline as well as its business overall. Specifically, the risks and uncertainties the Company faces with respect to its lead program, elagolix, include the risk that the elagolix endometriosis Phase III clinical trials will fail to demonstrate that elagolix is safe and effective; the risk that elagolix Phase III clinical trials will be delayed for regulatory or other reasons; the risk that the elagolix uterine fibroids clinical program will not proceed to later stage clinical trials; and the risks associated with the Company's dependence on AbbVie for elagolix Phase III development, commercial manufacturing and marketing and sales activities. In addition, the Company faces risks and uncertainties with respect to the rest of the Company's R & D pipeline including; risk that the Company's VMAT2 Phase III program will be delayed for regulatory or other reasons; risk that the VMAT2 Phase III clinical program will fail to demonstrate that NBI-98854 is safe and effective; risk that the guidance provided by the FDA in the End-of-Phase II meeting may be modified or may not lead to regulatory approval; risk that the Company will be unable to file an IND for Tourette syndrome or initiate clinical trials for regulatory or other reasons; risk that the Company's research programs will not identify pre-clinical candidates for further development; and risk that the Company's other product candidates will not be found to be safe and effective. With respect to its business overall, the Company faces risk that it will be unable to raise additional funding required to complete development of all of its product candidates; risk relating to the Company's dependence on contractors for clinical drug supply, commercial manufacturing and marketing and sales activities; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products if approved. The Company also faces the other risks described in the Company's annual report on Form 10-K for the year ended December 31, 2013 and quarterly report on Form 10-Q for the quarter ended March 31, 2014. Neurocrine undertakes no 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,	
	2014	**2013**	**2014**	**2013**
Revenues:				
License fees	$ -	$ 730	$ -	$ 1,460
Total revenues	-	730	-	1,460

Operating expenses:				
Research and development	10,161	10,527	18,733	20,840
General and administrative	4,200	3,370	8,353	6,762
Total operating expenses	14,361	13,897	27,086	27,602
Loss from operations	(14,361)	(13,167)	(27,086)	(26,142)
Other income:				
Gain (loss) on sale/disposal of assets	5	19	(5)	32
Deferred gain on real estate	805	781	1,609	1,563
Investment income, net	167	121	256	224
Other income, net	3	4	3	6
Total other income	980	925	1,863	1,825
Net loss	$ (13,381)	$ (12,242)	$ (25,223)	$ (24,317)
Net loss per common share:				
Basic and diluted	$ (0.18)	$ (0.18)	$ (0.35)	$ (0.36)
Shares used in the calculation of net loss per common share:				
Basic and diluted	75,879	66,799	73,085	66,700

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

	June 30, 2014	December 31, 2013
Cash, cash equivalents and short-term marketable securities	$ 194,656	$ 145,739
Other current assets	2,919	2,723
Total current assets	197,575	148,462

Property and equipment, net	2,239	1,771
Long-term investments, available for sale	65,282	-
Restricted cash	4,443	4,443
Total assets	$ 269,539	$ 154,676
Current liabilities	$ 12,053	$ 11,699
Long-term liabilities	20,641	22,567
Stockholders' equity	236,845	120,410
Total liabilities and stockholders' equity	$ 269,539	$ 154,676

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Investor Relations, (858) 617-7600