



Neurocrine Biosciences Reports First Quarter 2014 Results

April 30, 2014

-Endometriosis Phase III Violet Petal Study Completes Screening- -Tardive Dyskinesia Phase III Initiation Planned for Second Half of 2014- -Over \$270 Million to Fund Clinical Pipeline-

SAN DIEGO, April 30, 2014 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended March 31, 2014. For the first quarter of 2014, the Company reported a net loss of \$11.8 million, or \$0.17 loss per share, compared to a net loss of \$12.1 million, or \$0.18 loss per share, for the same period in 2013.

The Company's balance sheet at March 31, 2014 reflected cash, cash equivalents, investments and receivables of \$272.3 million compared to \$146.8 million at December 31, 2013. During the quarter, the Company completed a public offering of eight million shares of common stock that resulted in net proceeds of approximately \$133 million.

"The capital raise during the first quarter greatly strengthened our financial position, providing us with the funding to move NBI-98854 aggressively into Tourette syndrome and to ultimately advance our other research programs into the clinic," said Kevin Gorman, Ph.D., President and Chief Executive Officer of Neurocrine Biosciences. "We are currently awaiting our End-of-Phase-II meeting with the FDA for tardive dyskinesia while actively preparing for the subsequent Phase III studies. Additionally, AbbVie has recently completed patient screening for the first of the two elagolix Phase III endometriosis studies."

Research and development expenses decreased to \$8.6 million during the first quarter of 2014 from \$10.3 million during the same period in 2013. This decrease was due to lower external clinical development expenses related to the Company's VMAT2 inhibitor, NBI-98854, which substantially completed Phase II development in late 2013 and is currently preparing for Phase III development. General and administrative expenses increased from \$3.4 million in the first quarter of 2013 to \$4.2 million for the first quarter of 2014, primarily due to higher share-based compensation expense.

Updated 2014 Financial Guidance

As a result of the recent capital raise the Company is updating its financial guidance for 2014. Consistent with prior guidance, the Company expects to have a net cash burn from operations of approximately \$43 million to \$47 million in 2014, with expenses for 2014 approximating \$60 million to \$64 million. The Company continues to expect a net loss for 2014 of \$56 million to \$61 million; however the expected net loss per share will decrease to \$0.75 to \$0.81 loss per share based on approximately 75 million basic shares outstanding. Additionally, the Company now expects to end 2014 with approximately \$230 million in cash, investments and receivables.

Pipeline Highlights

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. This study recently completed recruiting and screening of subjects and final patient randomization is anticipated later this month.

AbbVie has also initiated 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.

AbbVie is also currently conducting a Phase IIb study of elagolix in uterine fibroids. This study is assessing uterine blood loss in 520 women with heavy uterine bleeding due to uterine fibroids.

VMAT2 Update

The Company has requested an End-of-Phase-II meeting with the FDA for NBI-98854 in tardive dyskinesia. The Company will submit a meeting briefing package, along with a proposed Phase III protocol, to the FDA this month. This End-of-Phase-II meeting is expected to occur in June 2014.

Upon completion of this meeting, the Company anticipates initiating the pivotal Phase III program of NBI-98854 during the second half of 2014. The Company is currently identifying and qualifying investigator sites for the Phase III program, as well as preparing drug product, aligning support vendors, and finalizing the plans for patient recruitment.

Additionally, the Company has completed appropriate preclinical studies to support the advancement of NBI-98854 into clinical trials for individuals suffering from Tourette syndrome. The Company is meeting with the FDA to discuss the proposed clinical protocols and expects to open the investigational new drug application for Tourette syndrome and commence the clinical program in patients later this year.

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 866-952-1908 (US) or 785-424-1827 (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 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 business and finances in general, as well as risks and uncertainties associated with the Company's R & D pipeline and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's R & D pipeline include risk that elagolix, the company's lead clinical program, will fail to demonstrate that elagolix is safe and effective; risk that elagolix Phase III clinical trials will be delayed for regulatory or other reasons; and risks associated with the Company's dependence on corporate collaborators for 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 clinical candidates will not be found to be safe and effective; risk that the Company's VMAT2 clinical candidates will not proceed to later stage clinical trials; and risk that the Company's research programs will not identify pre-clinical candidates for further development. With respect to its pipeline 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 contract manufacturers for clinical drug supply; risks associated with the Company's dependence on corporate collaborators for 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; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2013. 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)

	Three Months Ended	
	March 31,	
	2014	2013
	(unaudited)	
Revenues:		
License fees	\$ -	\$ 730
Total revenues	-	730
Operating expenses:		
Research and development	8,572	10,313
General and administrative	4,153	3,392
Total operating expenses	12,725	13,705
Loss from operations	(12,725)	(12,975)
Other income:		
Interest and other income	89	105
Gain on sale of assets, net	794	795
Total other income	883	900
Net loss	<u>\$ (11,842)</u>	<u>\$ (12,075)</u>
Net loss per common share:		
Basic and Diluted	\$ (0.17)	\$ (0.18)
Shares used in the calculation of net loss per common share:		
Basic and Diluted	70,260	66,600

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

	March 31,	December 31,
	2014	2013
	(unaudited)	
Cash, cash equivalents and short-term marketable securities	\$219,862	\$ 145,739
Other current assets	1,873	2,723

Total current assets	221,735	148,462
Property and equipment, net	1,798	1,771
Long-term investments	51,320	-
Restricted cash	4,443	4,443
Total assets	<u>\$279,296</u>	<u>\$154,676</u>
Current liabilities	\$10,608	\$ 11,699
Long-term liabilities	21,631	22,567
Stockholders' equity	247,057	120,410
Total liabilities and stockholders' equity	<u>\$279,296</u>	<u>\$154,676</u>

SOURCE Neurocrine Biosciences, Inc.

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