



Neurocrine Biosciences Reports First Quarter 2004 Results

May 3, 2004

Company Will Host a Conference Call and Webcast Today, Monday, May 3, 2004

SAN DIEGO, May 3 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the quarter ended March 31, 2004. For the first quarter, the Company reported a net loss of \$12.4 million, or \$0.35 per share compared with a net loss of \$13.4 million, or \$0.43 per share, for the same period in 2003.

Revenues for the first quarter of 2004 were \$16.9 million compared with \$37.7 million for the respective period last year. The decrease in revenues of \$20.8 million is primarily due to lower sponsored development revenue associated with the winding down of the indiplon registration clinical program, offset by licensing fee revenue reflected in the collaboration agreement with Pfizer Inc (Pfizer). During the first quarter of 2004, under the Pfizer collaboration agreement, the Company recognized \$4.0 million in the form of sponsored development funding and an additional \$10.9 million resulting from license fees. During the first quarter of 2003 the Company realized \$29.3 million from Pfizer for sponsored development funding and an additional \$5.1 million recognition of license fees.

Research and development expenses decreased to \$26.4 million for the first quarter 2004 compared with \$48.3 million for the respective period in 2003. This \$21.9 million decrease in research and development expenses is primarily due to our Phase III program for indiplon that is nearing completion, offset by increased research and development expenses in other programs.

General and administrative expenses increased to \$5.3 million for the first quarter 2004 compared with \$4.7 million during the same period last year. The increase in expenses from 2003 to 2004 resulted primarily from the addition of administrative personnel to support the expanding research and development activities, marketing and business development.

The Company's balance sheet on March 31, 2004 reflected total assets of \$577.3 million, including cash, cash equivalents, marketable securities of \$371.7 million compared with balances at December 31, 2003 of \$555.0 million and \$453.2 million, respectively. The decrease in cash balances resulted primarily from the purchase of the indiplon royalty stream from Wyeth for \$50.0 million cash combined with the operating loss for the quarter.

"As we wind down our Phase III clinical registration program for indiplon, we will focus on the completion of data integration and dose selection for market differentiation to support submission of our New Drug Applications (NDAs) for indiplon which will include data from 69 clinical trials and approximately 7,000 subjects making this one of the largest, most robust clinical programs in the sleep class," said Paul Hawran, Executive Vice President and Chief Financial Officer of Neurocrine Biosciences. "Upon filing, our efforts will then concentrate on building and developing our sales and marketing infrastructure to support our research and development programs and to prepare for the launch and commercialization of indiplon as we continue our transition to a more fully integrated pharmaceutical company," added Hawran.

First Quarter Highlights

Indiplon

Neurocrine completed and reported positive results in seven Phase III clinical trials for indiplon:

Immediate Release Formulation:

- * Two week efficacy and safety trial with two dose levels in 360 elderly patients
- * "RESTFUL" long term, three month efficacy and safety trial with two dose levels in 700 adult patients
- * Six month safety trial with two dose levels in 120 elderly patients

Modified Release Formulation:

- * One night efficacy and safety trial with two dose levels in 325 adult subjects
- * Two week efficacy and safety trial in 220 elderly patients
- * "SLEEP" long term, three month efficacy and safety trial with two dose levels in 740 adult patients
- * 35 day efficacy and safety trial with two dose levels in 340 elderly patients

Based on the results of the Phase III clinical trials, the Company is currently assembling the documentation to submit an NDA. The objectives and timing of the filing for both NDAs will be announced after Neurocrine and Pfizer finalize the strategy for market differentiation including dose selection, product positioning and labeling.

GnRH for Women's Health Disorders and Prostate Cancer

The second generation GnRH candidate, NBI-56418, for endometriosis and uterine fibroids is currently completing Phase I clinical studies. The current study is a Phase I combination single dose, followed by multiple escalating doses in approximately 50 pre-menopausal women. The study is assessing the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of the compound.

- * Completed the first cohort of subjects for the multiple dosing portion of the trial and escalating to higher doses.
- * Initiated Phase I single dose in normal healthy males.
- * Initiation of Phase IIa studies are planned to begin before the end of the year.
- * A back-up compound is scheduled to enter a Phase I trial during the third quarter.

CRF for Stress Related Disorders

The Corticotropin Releasing Factor (CRF) program (CRF small molecule antagonist) partnered with GlaxoSmithKline (GSK) has identified multiple unique preclinical compounds that are in various stages of development for anxiety, depression and irritable bowel syndrome (IBS).

Urocortin

Urocortin II (UCN-2), a recently discovered endogenous peptide ligand of the CRF-R2 receptor is present in the cardiovascular system, notably the heart and cerebral arterial system and is expressed in cardiac, brain, and gastrointestinal tissues. Expression of cardiac UCN-2 is increased in experimental models of heart failure, and patients with mild to moderate heart failure have been shown to have increased levels of plasma UCN-2. In pre-clinical studies, UCN-2 demonstrated potent inotropic, vasodilator, cardio-protective, and diuretic effects.

- * Final preclinical safety study currently underway.
- * Phase I trials are expected to begin this year targeting acute congestive heart failure.

Altered Peptide Ligand (APL) for Multiple Sclerosis

A Phase II clinical trial with NBI-5788 for the treatment of relapsing MS was initiated July 2003 to evaluate the safety and tolerability of 5 mg injections of NBI-5788 administered in 5 weekly doses followed by eight monthly doses for a period of nine months. A previous Phase II study of NBI-5788 with patients receiving subcutaneous injections of 5, 20 and 50 mg or placebo suggested clinical improvement for those patients receiving the lowest dose (5 mg). Based on the results from this earlier study, this new trial will further identify the efficacy and safety of NBI-5788 at this 5 mg dose.

- * Enrollment is currently ongoing in 25 sites throughout the US and Canada and is expected to complete toward the end of 2004.
- * Results from this second Phase II trial are expected in 2005.

Altered Peptide Ligand for Type I Diabetes

Neurocrine has successfully completed four Phase I/II clinical trials with NBI-6024 for Type I Diabetes.

- * Completed enrollment in a Phase II, dose response, efficacy and safety trial in approximately 200 adults/adolescents with new onset Type 1 diabetes.
- * Preliminary results are expected in 2005.

D2 Receptor Agonist

Neurocrine acquired the rights from Pharmacia for NBI-69733, a selective dopamine D2 receptor agonist, to develop indications related to male and female sexual dysfunction.

- * A Phase II trial in male erectile dysfunction (MED) is currently being planned.

Research Overview

Neurocrine's Research Department continues to progress small molecule antagonists against G-protein coupled receptors (GPCRs) into clinical development. It is believed one or more will progress into clinical development within the year. They include the following:

- * MC-4 is at the development compound stage and represents a novel target for the treatment of obesity, cachexia and pain.
- * MCH is currently at the advanced lead compound stage and is believed to play an important role in the treatment of obesity, anxiety and depression.
- * New Insomnia Program is at the advanced lead stage to treat various sleep disorders.

Conference Call and Webcast

Neurocrine will also host a live conference call and Webcast to discuss its first quarter financial results and provide a Company update today, Monday, May 3, 2004 at 11:00 a.m. Eastern Time (ET) / 8:00 a.m. Pacific Time (PT). Participants may access the live conference call by dialing 1-800-905-

0392 (U.S.) or 785-832-0326 (International). The call can also be accessed via the Webcast through the Company's website at <http://www.neurocrine.com> or alternatively through a link provided by PR Newswire at <http://www.firstcallevnts.com/service/ajwz405325797gf12.html>. A replay of the Conference Call will be available approximately one hour after the conclusion of the call by dialing 1-888-567-0677 (U.S.) or 402-530-0419 (International) and will be archived until Monday, May 17, 2004.

Neurocrine Biosciences, Inc. is a product-based biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including insomnia, certain female and male disorders, anxiety, depression, diabetes, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, and autoimmunity. 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 and research programs in general including, but not limited to, risk and uncertainties associated with, or arising out of, drug discovery, pre-clinical and clinical development of products including risk that the Company's Urocortin and CRF research programs will not lead to clinical candidates, that the GnRH receptor antagonist, D2 receptor agonist and altered peptide ligand clinical candidates will not proceed to later stage clinical trials and risks and uncertainties associated with the Company's indiplon Phase III program and planned regulatory activities. Specifically, the risks and uncertainties the Company faces with respect to its indiplon program include, but are not limited to, risk that indiplon may not successfully proceed through Phase III clinical trials including the risk that Phase III clinical trials may fail to demonstrate that indiplon is safe and effective in treating humans and the risk that additional clinical studies may be required to support filings for regulatory approval; risk that the Company may not complete indiplon Phase III clinical trials on the Company's projected timelines for various reasons, including the risk that the clinical investigators and contract research organizations upon which the Company relies to conduct its clinical programs may not be diligent, careful or timely, and may make mistakes, in the conduct of the programs; risk relating to the Company's dependence on contract manufacturers for clinical drug supply and compliance with regulatory requirements for marketing approval; risk that the Company may not successfully co-ordinate the completion and submission of planned regulatory filings on the Company's projected timelines; risk that the Company may not receive regulatory approval for indiplon or approval may be delayed; 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; risk that the Company will be unable to raise additional funding required to complete development of all of its product candidates; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2003. 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 for loss per share data)

	Three Months Ended	
	March 31,	
	2004	2003
	(unaudited)	(unaudited)
Revenues:		
Sponsored research and development	\$ 5,369	\$ 30,725
License fees	11,319	6,667
Grant income	253	324
Total revenues	16,941	37,716
Operating expenses:		
Research and development	26,388	48,324
General and administrative	5,283	4,744
Total operating expenses	31,671	53,068
Loss from operations	(14,730)	(15,352)
Other income and (expenses):		
Interest and other income, net	2,353	2,065
Other income, net	-	48
Loss before income tax expense	(12,377)	(13,239)
Income tax expense	3	151
Net loss	\$ (12,380)	\$ (13,390)
Loss per common share:		
Basic and Diluted	\$ (0.35)	\$ (0.43)
Shares used in the calculation of loss per common share:		
Basic and Diluted	35,527	30,789

NEUROCRINE BIOSCIENCES, INC.

Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2004 (unaudited)	December 31, 2003 (unaudited)
Cash, cash equivalents and marketable securities	\$ 371,733	\$ 453,168
Other current assets	9,917	18,641
Total current assets	381,650	471,809
Property and equipment, net	79,044	56,236
Prepaid royalties	95,000	-
Other non-current assets	21,575	26,910
Total assets	\$ 577,269	\$ 554,955
Current liabilities	\$97,536	\$ 110,012
Long-term liabilities	54,328	53,823
Stockholders' equity	425,405	391,120
Total liabilities and stockholders' equity	\$ 577,269	\$ 554,955

SOURCE Neurocrine Biosciences, Inc.