



Neurocrine Biosciences Reports First Quarter 2001 Results; Company Updates Progress in Clinical & Research Pipeline

April 30, 2001

SAN DIEGO, April 30 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the first quarter ended March 31, 2001. The Company reported a net loss of \$11.5 million, or \$0.45 per share, for the three months ended March 31, 2001 compared with \$6.0 million, or \$0.28 per share, for the respective period in 2000.

Revenues rose 25% to \$3.5 million for the first quarter 2001 as compared with \$2.8 million for the respective period last year. The increase in revenues from last year to this year resulted primarily from revenues received under the Taisho Pharmaceuticals agreement.

Research and development expenses increased to \$15.2 million for the first quarter 2001 compared with \$7.8 million for the respective period in 2000. General and administration expenses increased slightly to \$2.4 million for the first quarter 2001 compared with \$2.2 million during the same period last year. Increased expenses primarily reflect higher costs associated with expanding development activities and the addition of scientific personnel. Currently, the company has 15 ongoing programs in its research and development pipeline as compared to 12 programs at this time last year. Five of these programs are in clinical development, three programs are in advanced pre-clinical development expected to enter human clinical trials in 2001 and seven programs in various stages of research.

The Company's balance sheet on March 31, 2001 reflected total assets of \$172.8 million, including cash, cash equivalents, marketable securities and accounts receivable of \$156.9 million compared with balances at December 31, 2000 of \$186.0 million and \$170.6 million, respectively. The decline in cash, cash equivalents, marketable securities and accounts receivable represents funding of current period clinical development projects and the addition of scientific personnel.

"We are especially pleased with both the first quarter financial results, which were better than expected, and with the continued progress of our clinical development programs. We are currently poised to initiate Phase III studies, the final clinical phase of development, for two of our products later this year. During the first quarter Neurocrine announced positive clinical trial results in sedative activity of NBI-34060 for insomnia. Neurocrine's development team also selected a modified release (MR) formulation of NBI-34060 for sleep maintenance. The two formulations of NBI-34060 (immediate release and modified release) are designed to address the needs of the entire insomnia population: for sleep initiation, night awakenings and sleep maintenance," stated Paul Hawran, Executive Vice President and Chief Financial Officer of Neurocrine Biosciences.

"Results of a Phase II clinical trial comparing NBI-34060, Ambien(TM) and zopiclone relative to placebo during Middle of the Night (MOTN) dosing demonstrated that NBI-34060 does not lead to next-day hangover effects while both Ambien(TM) and zopiclone exhibited statistically significant measures of next-day adverse side effects of residual sedation. Results of Phase I pharmacokinetic studies demonstrated that NBI-34060 works as a sedative- hypnotic with no major differences in the pharmacokinetics between young adults and elderly subjects in a randomized, double-blind, placebo-controlled clinical study with multiple doses of NBI-34060 nor are there differences in the pharmacokinetics in males and females. We have successfully completed enrolling 14 clinical studies involving over 830 subjects to date and based on preliminary data are preparing for pivotal Phase III trials for NBI-34060 starting in Q3 2001. We expect to announce the results of the ongoing Phase II clinical trials in patient populations with transient and chronic insomnia at the end of the second quarter of this year," added Hawran.

Additional Clinical Development Progress:

- Neurocrine continued enrollment in its Phase I/II clinical trial for Glioblastoma and is on track to complete this study and initiate Phase III studies later this year.
- Neurocrine announced the expansion of its clinical program for NBI-6024 in Type I diabetes to the United States and that the Company will initiate Phase IIB trials in early second half of 2001.
- Neurocrine announced positive Phase I clinical trial results with its proprietary CRF1 receptor antagonist compound for depression and anxiety. This Phase I randomized, double-blind, placebo-controlled, single-dose trial was conducted in 48 normal healthy volunteers and was designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics, including endocrine profiles over a wide range of six escalating doses. Initial pharmacokinetic evaluation indicated rapid absorption, linear dose-proportionality with no safety issues.
- Neurocrine scientists presented data on its GnRH small molecule antagonist program at a peer review scientific meeting in Switzerland. In this presentation, it was reported that they have developed potent orally active compounds for the modulation for the reduction of hormone levels in the treatment of endometriosis, fibroids and prostate cancer. A development candidate has been selected and the Company expects to initiate Phase I clinical studies later this year.

Hawran continued, "In our research pipeline we have developed accelerated processes to identify and develop high potential, high value compounds to deliver three new drug candidates over the next five years. While Neurocrine uses all of the traditional technologies of drug discovery, we have taken science to the next step, with a new technology we call Multi-Channel Discovery or MCD(TM). MCD(TM) is a system applied to drug design, which is driven by the power of traditional medicinal chemistry and accelerated by computational methodologies to guide the synthesis of highly active small molecules for a specific molecular target, importantly, derived from multiple series."

"We have made important scientific advances in our seven research programs focusing on CNS, psychiatric and metabolic therapeutic areas. Neurocrine scientists continue to develop new targets and are also exploiting new indications for our existing technologies such as CRF receptor antagonists for additional stress related diseases such as irritable bowel syndrome and IL-4 fusion toxin (NBI-3001) for peripheral cancers," added Hawran.

Neurocrine Biosciences, Inc. is a product-based biopharmaceutical company focused on neurologic and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including insomnia, anxiety, depression, cancer and diabetes.

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 contains 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 research and development programs and business and finances including, but not limited to, risks and uncertainties associated with, or arising out of, drug discovery, pre-clinical and clinical development of products including risk that research may not generate development candidates, development candidates will not successfully proceed through early clinical trials or that in later stage clinical trials will not show that they are effective in treating humans; determinations by regulatory and governmental authorities; changes in relationships with strategic partners and dependence upon strategic partners for performance of clinical and commercialization activities under collaborative agreements including potential for any collaboration agreement to be terminated without any product success; uncertainties relating to patent protection and intellectual property rights of third parties; impact of competitive products and technological changes; availability of capital and cost of capital; and other material risks. A more complete description of these risks can be found in the Company's Form 10K for the year ended December 31, 2000 and the current form 10Q each of which should be read before making any investment in Neurocrine common stock. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

NEUROCRINE BIOSCIENCES, INC.

Statement of Operations

(unaudited; in thousands except for loss per share data)

	Three Months Ended	
	March 31,	
	2001	2000
Revenues:		
Sponsored research and development	\$2,965	\$1,522
License and option fees	229	1,000
Grant income and other revenues	294	256
Total revenues	3,488	2,778
Operating expenses:		
Research and development	15,190	7,771
General and administrative	2,377	2,233
Total operating expenses	17,567	10,004
Loss from operations	(14,079)	(7,226)
Other income and (expenses):		
Interest and other income, net	2,533	1,514
Other income and expenses, net	83	(135)
Loss before taxes	(11,463)	(5,847)
Income taxes	\$--	200
Net loss	\$(11,463)	\$(6,047)
Loss per common share:		
Basic and diluted	\$(0.45)	\$(0.28)
Shares used in the calculation of		
loss per common share:		
Basic and diluted	25,407	21,771

Balance Sheet
(in thousands)

March 31, December 31,

	2001 (unaudited)	2000
Cash, cash equivalents and marketable securities	\$155,689	\$164,670
Other current assets	3,195	7,735
Total current assets	158,884	172,405
Property and equipment, net	11,510	11,300
Other assets	2,443	2,257
Total assets	\$172,837	\$185,962
Current liabilities	\$12,093	\$14,959
Long-term liabilities	7,452	7,795
Stockholders' equity	153,292	163,208
Total liabilities and stockholders' equity	\$172,837	\$185,962

MAKE YOUR OPINION COUNT - [Click Here](#)
<http://tbutton.prnewswire.com/prn/11690X64381654>

SOURCE Neurocrine Biosciences, Inc.

Web site: <http://www.neurocrine.com>

CONTACT: Claudia Jones or Paul Hawran of Neurocrine Biosciences, 858-658-7600