
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of the earliest event reported): January 29, 2004

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	0-28150 (Commission File Number)	33-0525145 (IRS Employer Identification No.)
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10555 Science Center Drive, San Diego, CA (Address of principal executive offices)	92121 (Zip Code)
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Registrant's telephone number, including area code: **(858) 658-7600**

N/A

(Former name or former address, if changed since last report.)

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.

(c) EXHIBITS. The following exhibits are filed herewith:

<u>Exhibit</u> <u>Number</u>	<u>Description of Exhibit</u>
99.1	Press Release dated January 29, 2004

ITEM 12. RESULTS OF OPERATION AND FINANCIAL CONDITION

On January 29, 2004, Neurocrine Biosciences, Inc. announced its financial results for the year ended December 31, 2003. The full text of the press release issued in connection with the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.6. of Form 8-K, the information in this Current Report of Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: January 29, 2004

NEUROCRINE BIOSCIENCES, INC.

/s/ PAUL W. HAWRAN

Paul W. Hawran
Executive Vice President
and Chief Financial Officer

FOR IMMEDIATE RELEASE

Contact at Neurocrine Biosciences
 Claudia Jones or Elizabeth Foster
 (858) 658-7600

NEUROCRINE BIOSCIENCES REPORTS FOURTH QUARTER AND YEAR-END 2003 RESULTS

COMPANY PROVIDES UPDATE ON CLINICAL PROGRAMS

San Diego, CA, January 29, 2004 - Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the fourth quarter and year ended December 31, 2003. For the three months ended December 31, 2003, the Company reported a net profit of \$3.2 million or \$0.09 diluted earnings per share compared to a net loss of \$38.8 million or \$1.27 per share for the same period last year. During the 4th quarter, the Company realized a gain of \$18.0 million related to the sale of its current corporate facility. For the year ended December 31, 2003, the Company had a net loss of \$30.3 million, or \$0.93 per share compared with a net loss of \$94.5 million, or \$3.10 per share in 2002.

Revenues for the fourth quarter of 2003 were \$27.1 million compared with \$3.9 million for the same period last year. Revenues for the year ended December 31, 2003, were \$139.1 million, compared with \$18.0 million for 2002. The increase in revenues for the three months and year ended December 31, 2003 resulted primarily from reimbursement by Pfizer of clinical development expenses associated with the *indiplon* program of \$13.6 million and \$90.9 million, respectively. In addition, the Company recognized license fee revenues arising from the Pfizer collaboration of \$10.9 million and \$38.0 million in the same periods.

Research and development expenses decreased by \$2.5 million to \$39.1 million for the fourth quarter of 2003 compared with \$41.6 million for the respective period in 2002, primarily resulting from the completion of enrollment of the Phase III *indiplon* studies. For the year ended December 31, 2003, research and development expenses were \$177.3 million compared to \$108.9 million last year, representing a \$68.4 million increase. The increased year-to-date expenses primarily reflect higher costs associated with significant development activities, particularly the *indiplon* Phase III program. In addition to the *indiplon* program, the Company has 13 programs in various stages of research and development. Additionally, personnel and laboratory costs increased during the same period due to the expansion of research and development activities.

General and administrative expenses were \$5.4 million for the fourth quarter 2003 compared with \$3.6 million for the same period in 2002. For the year ended December 31, 2003 general and administrative expenditures totaled \$20.6 million compared to \$12.7 million in 2002. The year-to-date increase in general and administrative expenses resulted primarily from increased professional fees associated with business development, and the addition of administrative personnel needed to support expanding research and development activities and implementation of our commercialization strategy.

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The Company's balance sheet at December 31, 2003 reflected total assets of \$555.0 million including cash, cash equivalents, marketable securities and current assets of \$471.8 million, compared with balances at December 31, 2002 of \$266.5 million and \$248.1 million respectively. The increase in cash balances at December 31, 2003 resulted primarily from the receipt of the initial license and collaboration payments from Pfizer totaling \$100.0 million and the sale of 3.75 million shares of common stock in a public offering which generated net cash proceeds of \$187.4 million, offset by capital acquisitions and operating losses.

A Year In Review

- Satisfied the requirements for the Hart-Scott Rodino Act in connection with Neurocrine's global collaboration with Pfizer.
- Expanded the senior management team with the addition of Dr. Wendell Wierenga as Executive Vice President of Research and Development, Robert J. Little as Senior Vice President of Commercial Operations and Lloyd Flanders as Senior Vice President of Development.
- Completed a successful follow-on offering of common stock, netting proceeds of \$187.4 million.
- Reported positive results from five clinical trials of *indiplon* as well as completed enrollment for *indiplon*'s Phase III registration program.
- Reported positive results in a Phase I clinical trial of its Gonadotropin-Releasing Hormone (GnRH) receptor antagonist compound for the treatment of endometriosis, uterine fibroids and prostate cancer.
- Advanced a second generation GnRH candidate into Phase I clinical trials assessing the safety, pharmacokinetics and pharmacodynamics of the compound.
- Initiated a Phase II clinical trial with NBI-5788 for Multiple Sclerosis. Results are expected in 2005.

"We anticipate 2004 to be a pivotal year for Neurocrine, as we transition from a research and development biotechnology company to a fully integrated pharmaceutical company," said Paul Hawran, Executive Vice President and Chief Financial Officer of Neurocrine Biosciences. "Having wrapped up enrollment in our Phase III clinical trials of *indiplon*, we have completed one of the largest clinical programs for the treatment of insomnia which included 62 clinical trials and approximately 7,000 subjects. In collaboration with our partners at Pfizer, we expect to file our New Drug Application (NDA) in mid-year."

"Additionally, we are expecting a continued reduction in our operating losses for 2004 and anticipate a slight loss for the year ending 2004 with cash reserves in excess of \$400.0 million. This loss could be higher subject to in-licensing of new product development opportunities. Notwithstanding, our forecasts are for the Company to cross over to profitability in 2005," added Hawran.

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Clinical Trial Update

***Indiplon* Immediate Release**

Trial	Design	Endpoints	# Patients	Results Expected
Two Week Efficacy and Safety	Two dose levels of <i>indiplon</i> versus placebo	Latency to Sleep Onset as reported by patient (LSO)	358 Elderly	Q1 04
Long Term Efficacy and Safety "RESTFUL" Study	Two dose levels of <i>indiplon</i> relative to placebo for sleep initiation insomnia	Latency to Sleep Onset measured by patient self reported outcomes (LSO)	700 Elderly	Q1 04
Six-Month Safety Extension Study	Open label extension study	Long term safety exposure	121 Elderly	Q1 04

***Indiplon* Modified Release**

Trial	Design	Endpoints	# Patients	Results Expected
Two Week Efficacy and Safety	One dose of <i>indiplon</i> versus placebo	Total Sleep Time as reported by patient (sTST)	223 Elderly	Q1 04
35-Day Inpatient/Outpatient Efficacy and Safety	Two dose levels of <i>indiplon</i> versus placebo	Wake After Sleep Onset (WASO) measured by polysomnography (PSG)	344 Elderly	Q1 04
Long Term Efficacy and Safety "SLEEP" Study	Two dose levels of <i>indiplon</i> relative to placebo for sleep maintenance insomnia	Total Sleep Time as reported by patient (sTST)	740 Adults	Q1 04

GnRH for Women's Health Disorders and Prostate Cancer

Enrollment in a Phase I second generation GnRH candidate, NBI-56418, for endometriosis and uterine fibroids was initiated in September. This trial is a combination single dose, followed by multiple escalating doses of NBI-56418 in approximately 50 pre-menopausal women. The study is assessing the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of the compound. Dosing has been completed in the first three cohorts of subjects and has begun the multiple dosing portion of the trial. Enrollment is expected to be completed by the end of the 1st 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).

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Urocortin

Urocortin II is a recently discovered endogenous peptide ligand of the CRF-R2 receptor present in the cardiovascular system, notably the heart and cerebral arterial system. Neurocrine has licensed Urocortin II (a 38 amino acid peptide) from the Clayton Foundation to further expand the Company's franchise in CRF. Neurocrine will continue to study the utility of this compound in endocrine, metabolic, and cardiovascular disorders and is expected to enter Phase I trials in the first half of this year.

Altered Peptide Ligand (APL) for Type I Diabetes and Multiple Sclerosis

Neurocrine has advanced two APL product candidates into Phase II clinical development, NBI-5788 for Multiple Sclerosis (MS) and NBI-6024 for Type I Diabetes. A Phase II clinical trial with NBI-5788 for the treatment of relapsing MS was initiated July 2003, evaluating 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. Completion of enrollment is expected toward the end of 2004. Results from this second Phase II trial are expected in 2005.

The Company has successfully completed four Phase I/II clinical trials with NBI-6024 for Type I Diabetes. Neurocrine is currently conducting a Phase II, dose response, efficacy and safety trial in approximately 200 adults/adolescents with new onset Type 1 diabetes. Enrollment will be completed in the 1st quarter 2004. Preliminary results from this trial are expected in late 2005.

D₂ Receptor Agonist for Erectile Dysfunction

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 proof of concept clinical study in the area of male erectile dysfunction (ED) is being planned.

Conference Call and Webcast

Neurocrine will also host a live conference call and Webcast to discuss its year-end financial results and provide a Company update Friday morning, January 30, 2004 at 11:00 AM Eastern Standard Time (EST) / 8:00 AM Pacific Standard Time (PST). Participants may access the live Conference Call by dialing 1-800-245-3043 (U.S.) or 1-785-832-0326 (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 PRNewswire at <http://www.firstcallevents.com/service/ajwz397957067gf12.html>. A replay of the Conference Call will be available by dialing 1-800-753-5207 (US) or 1-402-220-2156 (International) and will be archived until Friday, February 13, 2004.

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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 or Phase III clinical trials may fail to demonstrate that indiplon is safe and effective in treating humans; 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, 2002, and the Company's most recent report on Form 10-Q. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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NEUROCRINE BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations
(in thousands except for income (loss) per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2003	2002	2003	2002
	(unaudited)	(unaudited)	(unaudited)	
Revenues:				
Sponsored research and development	\$ 15,048	\$ 1,652	\$ 96,699	\$ 12,364
License fees and milestones	11,820	1,519	41,126	3,516
Grant income	267	707	1,253	2,165
Total revenues	27,135	3,878	139,078	18,045
Operating expenses:				
Research and development	39,087	41,565	177,271	108,939
General and administrative	5,419	3,586	20,594	12,721
Total operating expenses	44,506	45,151	197,865	121,660
Loss from operations	(17,371)	(41,273)	(58,787)	(103,615)
Other income and (expenses):				
Gain on sale of property	17,946	-	17,946	-
Interest income and expense, net	2,601	2,446	10,601	8,864
Other income and expense, net	17	40	(16)	215
Total other income	20,564	2,486	28,531	9,079
Net income (loss)	\$ 3,193	\$ (38,787)	\$ (30,256)	\$ (94,536)
Net income (loss) per common share:				
Basic and diluted	\$ 0.09	\$ (1.27)	\$ (0.93)	\$ (3.10)

Shares used in the calculation of income

(loss) per common share:

Basic	35,273	30,611	32,374	30,488
Diluted	37,459	30,611	32,374	30,488

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

	December 31, 2003	December 31, 2002
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 453,168	\$ 244,710
Other current assets	18,641	3,384
Total current assets	471,809	248,094
Property and equipment, net	56,236	14,102
Other non-current assets	26,910	4,343
Total assets	\$ 554,955	\$ 266,539
Current liabilities	\$ 110,012	\$ 32,479
Long-term liabilities	53,823	9,806
Stockholders' equity	391,120	224,254
Total liabilities and stockholders' equity	\$ 554,955	\$ 266,539