
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): November 3, 2003

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 Number</u>	<u>Description of Exhibit</u>
99.1	Press Release dated November 3, 2003

ITEM 12. RESULTS OF OPERATION AND FINANCIAL CONDITION

On November 3, 2003, Neurocrine Biosciences, Inc. announced its financial results for the quarter ended September 30, 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: November 3, 2003

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 THIRD QUARTER 2003 RESULTS

ENROLLMENT IN INDIPLON'S PHASE III REGISTRATION PROGRAM HAS BEEN COMPLETED

San Diego, CA, November 3, 2003 - Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended September 30, 2003. For the 3rd quarter, the Company reported a net loss of \$9.8 million, or \$0.31 per share compared with a net loss of \$20.2 million or \$0.66 per share for the same period last year. For the nine months, the Company reported a net loss of \$33.4 million as compared with \$55.7 million in the same period last year.

Revenues for the 3rd quarter of 2003 were \$29.3 million compared with \$5.0 million for the same period last year. Revenues for the nine months ended September 30, 2003, were \$111.9 million, compared with \$14.2 million for the same period in 2002. The increase in revenues for the three and nine months ended September 30, 2003 resulted primarily from reimbursement of clinical development expenses associated with the *indiplon* program by Pfizer of \$16.1 million and \$77.3 million, respectively. In addition, the Company recognized \$10.9 million and \$27.0 million, respectively in license fee revenues arising from the Pfizer collaboration.

Research and development expenses increased to \$37.5 million for the 3rd quarter 2003 compared with \$24.2 million for the respective period in 2002. For the nine months ended September 30, 2003, research and development expenses were \$138.2 million compared with \$67.4 million for the same period last year. Increased expenses primarily reflect higher costs associated with expanding development activities, particularly the *indiplon* Phase III program. The Company currently has 17 programs in various stages of research and development, including seven programs in clinical development. Additionally, personnel and laboratory costs related to the expansion of research activities increased during the same period. General and administrative expenses increased to \$5.3 million for the 3rd quarter 2003 compared with \$3.3 million for the same period last year. For the nine months ended September 30, 2003 general and administrative expenditures totaled \$15.2 million compared with \$9.1 million in 2002. The increased cost resulted primarily from increased marketing related costs, increased professional fees associated with business development, and increased insurance costs.

The Company's balance sheet on September 30, 2003 reflected total assets of \$552.4 million, including cash, cash equivalents, marketable securities and current receivables of \$459.2 million compared with balances at December 31, 2002 of \$266.5 million and \$245.0 million, respectively. The increase in cash balances at September 30, 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.

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Highlights for the Third Quarter

- >> The Company also announced today the completion of enrollment in its Phase III registration program with *indiplon* for multiple insomnia indications.
- >> Completed a follow-on offering of 3.75 million shares of common stock which netted an additional \$187.4 million. This funding will allow the Company to pursue acquisitions of products or companies to further strengthen our product pipeline and advance our commercialization strategy.
- >> Released positive results in the first Phase III trial of the modified release formulation of *indiplon* for patients with chronic insomnia.
 - Patients receiving nightly administration of 30 mg of *indiplon* over a two-week period demonstrated statistically significant improvements in the primary endpoint of patient reported Total Sleep Time (sTST) relative to placebo for both week one (p<0.0001) and week two (p=0.0006).
 - Secondary endpoints also demonstrated statistically significant results in additional measures of sleep maintenance and patient reported Latency to Sleep Onset (LSO).
 - Patients exhibited no evidence of next day impairment or drowsiness.
 - Patient and investigator reported outcomes showed significant improvement compared to placebo.
 - Data confirmed patients with chronic insomnia fell asleep more rapidly and stayed asleep longer with the effect being sustained over the full two-week period.
- >> Wendell Wierenga joined Neurocrine Biosciences as the Executive Vice President of Research and Development.
- >> Announced the initiation and enrollment of a Phase II clinical trial for NBI-5788 for multiple sclerosis (MS) in approximately 150 patients with relapsing MS to evaluate safety and tolerability. Results from this Phase II trial are expected in 2005.
- >> Began enrollment in Phase I clinical trials for a second generation GnRH candidate for endometriosis and uterine fibroids.
- >> Completed four Phase I/II clinical trials with NBI-6024 for Type I Diabetes. The Company is currently conducting a Phase II, dose-response, efficacy and safety trial in approximately 200 adults/adolescents with new onset Type 1 diabetes. Enrollment is expected to be completed in the first quarter of 2004 with preliminary results expected in late 2005.

Neurocrine is now approaching completion of one of the most comprehensive clinical programs with its compound, *indiplon*, addressing the multiple needs of both younger and older adult patients with insomnia such as sleep initiation, sleep maintenance, middle of the night awakening, and long term administration. Upon completion of the data analysis for the full clinical program for both the immediate and modified release formulations of *indiplon*, the Company will include data for the New Drug Application (NDA) package filing from 62 clinical trials and approximately 7,000 subjects making this one of the largest, most robust clinical programs in the sleep class. To date, the Company has completed 51 clinical trials with *indiplon* immediate and modified release formulations, and

has enrolled over 6,700 patients for chronic and transient insomnia. The data reported from these trials have consistently met both primary and secondary endpoints demonstrating the efficacy and safety of *indiplon*. The results from the remaining ongoing clinical trials for both the immediate and modified release formulations of *indiplon* will be announced later this year and continuing into the first half of next year. The Company is on track to file the NDA for both formulations of *indiplon* in the first half of 2004 for multiple insomnia indications.

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Below is a summary of the Company's ongoing *indiplon* clinical trial program.

***Indiplon* Immediate Release**

Trial	Design	Endpoints	# Patients	Results Expected
Middle of the Night Dosing	Randomized, placebo controlled, double-blind, parallel group.	Efficacy relative to placebo after MOTN administration.	264 Adults	Q4 03
Six-Month Efficacy and Safety Extension Study	Open label extension study.	Long term safety exposure	121 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 Adults	Q1 04
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

***Indiplon* Modified Release**

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)	342 Elderly	Q1 04
Two Week Efficacy and Safety	One dose of <i>indiplon</i> versus placebo	Total Sleep Time as reported by patient (sTST)	220 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

Positive results were achieved in a second Phase I trial for a proprietary, orally active small molecule GnRH (Gonadotropin-releasing Hormone) receptor antagonist in development for the treatment of endometriosis, uterine fibroids and prostate cancer. This multiple-dosing study evaluated the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of NBI-42902 in healthy pre-menopausal women demonstrating that the compound was rapidly absorbed after oral administration. The systemic exposure of the drug was proportional to the total dose given either once-a-day or twice-a-day and was similar between Day One and Day Seven of dosing indicating no evidence of accumulation, enzyme induction or inhibition. Initial pharmacodynamic evaluation indicated suppression of luteinizing hormone (LH) and follicle stimulating hormone (FSH) as expected, based on data from a previous study with the compound in post-menopausal women. Furthermore, gonadal suppression was achieved resulting in suppression of estrogen to levels anticipated to be therapeutic. Results demonstrated that NBI-42902 was well tolerated by all subjects with no discontinuations or serious adverse events. A second generation GnRH candidate, NBI-56418, advanced into Phase I clinical trials in September. This trial is a combination single dose, followed by multiple escalating doses of NBI-56418 in approximately 50 pre-menopausal women and will assess the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of the compound. Dosing has been completed in the first cohort of subjects.

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D₂ Receptor Agonist for Erectile Dysfunction

Neurocrine acquired rights from Pharmacia to develop indications related to male and female sexual dysfunction for NBI-69733, a selective dopamine D₂ receptor agonist, in the 1st quarter of 2003. The compound has demonstrated high intrinsic activity in animal models of sexual dysfunction. Initiation of a Phase I proof of concept clinical study in the area of male erectile dysfunction (ED) is planned for mid year 2004 in order to determine its potential safety and efficacy. ED affects nearly 77 million men in the world's seven major pharmaceutical markets, and PDE-5 inhibitors such as Viagra and Levitra are the only effective oral treatments. NBI-69733 may offer a more selective mechanism of action and an improved product profile to this currently underserved market.

CRF for Stress Related Disorders

The 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). The partnership intends to advance a compound into Phase I development in 2004. Urocortin II (a 38 amino acid peptide) has been licensed from the Clayton Foundation/Salk Institute to further expand Neurocrine's franchise in CRF. 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 will continue to study the application of this compound in endocrine, metabolic, and cardiovascular disorders and is expected to enter Phase I trials in early 2004.

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

Two APL product candidates have advanced 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 in July, 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. Results from this second Phase II trial are expected in 2005.

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

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>

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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, the Company's most recent report on Form 10-Q and the Company's most recent Prospectus Supplement. 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 loss per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenues:				
Sponsored research and development	\$ 17,580	\$ 3,574	\$ 81,651	\$ 10,712
License fees and milestones	11,319	831	29,306	1,997
Grant income	360	578	986	1,458
Total revenues	29,259	4,983	111,943	14,167
Operating expenses:				
Research and development	37,537	24,231	138,184	67,374
General and administrative	5,296	3,253	15,175	9,135
Total operating expenses	42,833	27,484	153,359	76,509
Loss from operations	(13,574)	(22,501)	(41,416)	(62,342)
Other income and (expenses):				
Interest income and expense, net	3,724	2,283	8,000	6,418
Other income and expense, net	16	(16)	(33)	175
Total other income and (expenses)	3,740	2,267	7,967	6,593

Net loss	\$	(9,834)	\$	(20,234)	\$	(33,449)	\$	(55,749)
Loss per common share:								
Basic and Diluted	\$	(0.31)	\$	(0.66)	\$	(1.07)	\$	(1.83)
Shares used in the calculation of loss per common share:								
Basic and Diluted		32,053		30,522		31,397		30,447

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

	September 30, 2003	December 31, 2002
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 442,777	\$ 244,710
Other current assets	21,597	3,384
Total current assets	464,374	248,094
Property and equipment, net	58,289	14,102
Other non-current assets	29,739	4,343
Total assets	\$ 552,402	\$ 266,539
Current liabilities	\$ 115,274	\$ 32,479
Long-term liabilities	50,299	9,806
Stockholders' equity	386,829	224,254
Total liabilities and stockholders' equity	\$ 552,402	\$ 266,539