
UNITED STATES
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): February 5, 2008

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other
jurisdiction of
incorporation or
organization)

0-22705
(Commission File
Number)

33-0525145
(IRS Employer Identification
No.)

12790 El Camino Real, San Diego, California
(Address of principal executive offices)

92130
(Zip Code)

Registrant's telephone number, including area code: **(858) 617-7600**

N/A

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4 (c))
-
-

TABLE OF CONTENTS

[ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION](#)

[ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS](#)

[SIGNATURES](#)

[EXHIBIT INDEX](#)

[EXHIBIT 99.1](#)

[Table of Contents](#)

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On February 5, 2008, Neurocrine Biosciences, Inc. announced its financial results for the fourth quarter and year ended December 31, 2007. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on 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.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) EXHIBITS.

Exhibit Number	Description of Exhibit
99.1	Press Release dated February 5, 2008

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: February 5, 2008

NEUROCRINE BIOSCIENCES, INC.

/s/ TIMOTHY P. COUGHLIN

Timothy P. Coughlin

Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
99.1	Press Release dated February 5, 2008

FOR IMMEDIATE RELEASE

Contact at Neurocrine Biosciences
Claudia Woodworth
(858) 617-7600

**NEUROCRINE BIOSCIENCES REPORTS FOURTH QUARTER
AND YEAR-END 2007 RESULTS**

SAN DIEGO, Feb. 5, 2008 - Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the fourth quarter and year ended December 31, 2007. For the three months ended December 31, 2007, the Company reported a net loss of \$128.0 million or \$3.35 loss per share compared to a net loss of \$14.7 million or \$0.39 loss per share for the same period last year. For the year ended December 31, 2007, the Company had a net loss of \$207.3 million, or \$5.45 loss per share compared with a net loss of \$107.2 million, or \$2.84 loss per share in 2006. The increase in net loss is primarily the result of a one-time non-cash impairment charge of \$94.0 million related to the write-off of the indiplon prepaid royalty during the fourth quarter of 2007. Additionally, the Company incurred a \$6.9 million charge related to a severance program enacted in December 2007.

Revenues for the fourth quarter of 2007 were \$0.5 million compared with \$9.4 million for the same period last year. The Company recognized \$0.5 million in license fee revenues during the fourth quarter of 2007 related to the licensing of the Japanese rights for indiplon to Dainippon Sumitomo Pharma Co. Ltd. (DSP). During the fourth quarter of 2006, the Company recognized license fee revenues arising from the Pfizer, Inc. (Pfizer) collaboration of \$0.7 million. Additionally, the Company recognized milestones related to CRF drug candidate development under the GlaxoSmithKline (GSK) agreement of \$8.0 million for the fourth quarter of 2006.

Revenues for the year ended December 31, 2007, were \$1.2 million, compared with \$39.2 million for 2006. The decrease in revenues for the year ended December 31, 2007 is primarily due to the cancellation of our collaboration agreement with Pfizer. The Company recognized \$6.5 million and \$6.6 million in the form of license fees and sponsored development funding, respectively under the Pfizer collaboration agreement for the year ended December 31, 2006. The sales force allowance earned under the collaboration agreement was \$16.5 million for 2006. The Company also recognized milestones under the GSK collaboration agreement of \$9.0 million during 2006.

Research and development expenses were \$24.3 million in the fourth quarter of 2007 compared to \$18.6 million for the fourth quarter of 2006, primarily resulting from severance costs of \$4.9 million and higher external development costs related to the GnRH clinical program, offset by lower laboratory and personnel costs. For the year ended December 31, 2007, research and development expenses were \$82.0 million compared to \$97.7 million last year. This \$15.7 million decrease in year-to-date research and development expenses is due to lower personnel and laboratory costs, a result of our staff reductions in 2006 and lower external development costs.

Sales, general and administrative expenses were \$10.8 million for the fourth quarter 2007 compared with \$7.1 million for the same period in 2006, a direct result of \$2.0 million in severance costs incurred in 2007, and increased marketing activities in the fourth quarter of 2007. For the year ended December 31, 2007 sales, general and administrative expenditures totaled \$37.5 million compared to \$54.9 million in 2006. The decrease in expenses is primarily a result of our severance program enacted during the third quarter of 2006.

The Company's balance sheet at December 31, 2007 reflected total assets of \$276.7 million including cash, cash equivalents, and marketable securities of \$179.4 million, compared with balances at December 31, 2006 of \$389.7 million

and \$182.6 million, respectively. The Company's cash reserves were replenished during the fourth quarter to beginning of year levels. This was achieved through receipt of the \$20.0 million upfront license fee from DSP for licensing of indiplon in Japan, and the sale and leaseback of the Company's campus which netted approximately \$61.0 million in cash.

Financial Guidance for 2008

Exclusive of any new partnering agreements, the Company expects to have a net loss of approximately \$75 to \$80 million for 2008, and the cash burn from ongoing operations in 2008 is expected to be approximately \$65 to \$70 million.

"As we begin 2008 we are focusing the Company's resources towards advancing our clinical pipeline, led by three Phase II programs. Our GnRH compound is now in two large Phase II studies and this important program, with its multiple disease targets, continues to progress in partnering discussions. Our CRF collaboration with GSK has multiple compounds in clinical development for both CNS and GI disorders. Additionally, our Urocortin 2 program is scheduled to complete its preclinical toxicology studies this year in order to continue its Phase II clinical program in acute decompensated heart failure. We look forward to moving these programs and our preclinical targets ahead this year," said Kevin C. Gorman, President and CEO of Neurocrine Biosciences.

Indiplon update

On December 12, 2007, we received an action letter from the FDA stating that indiplon 5mg and 10mg capsules are Approvable (Approvable Letter). The Approvable Letter did not raise any of the issues previously raised by FDA in the May 15, 2006 Approvable Letter.

The Approvable Letter spelled out the following new requirements:

- An additional objective/subjective clinical trial in the elderly.
 - A safety study assessing the rates of adverse events occurring with indiplon when compared to a marketed product.
 - A preclinical study to evaluate indiplon administration during the third trimester of pregnancy.
-

The Company has an end of review meeting to discuss the contents of the Approvable Letter scheduled with the FDA during the first quarter of 2008. We will provide an update on the results of that FDA meeting during our first quarter 2008 earnings call.

Pipeline Highlights

The Company's clinical development group and corporate partners are advancing its lead programs through development. Neurocrine scientists continue to build the Company's pipeline and meet the Company-wide goal of bringing one new compound into development each year.

GnRH Antagonists in Expanded Phase II Clinical Trials for Endometriosis

- In mid December, we completed enrollment of patients in the 6-month Phase IIb clinical trial with NBI-56418.
- A new tablet formulation has been selected based upon optimal manufacturing processes and tablet characteristics to be used in all future studies.
- An additional Phase IIb clinical trial with the new formulation tablet was initiated in 2007 utilizing clinical endpoints that incorporate recent guidance from the FDA.

The Company has completed enrollment in a Phase IIb study in which 252 patients with endometriosis will be treated over a 6-month period. This multi-center, randomized, double-blind, study includes three treatment groups, with two doses of NBI-56418, 150 mg once a day and 75 mg twice daily, and an active comparator, Depo-Provera®. In addition to confirming the effect of NBI-56418 on endometriosis symptoms, this study is designed primarily to assess the impact of longer term treatment on bone mineral density as measured by DXA scan at the conclusion of dosing and at 6-months and 12-months post-treatment. Topline results from the 6-month treatment period are expected in mid-2008. The study will continue after the treatment period for DXA scans and safety assessments. The 6-month results, together with data from the other Phase II

studies, will be the basis for securing agreement on a registration plan with the FDA.

The Company is also conducting two additional randomized placebo controlled Phase II clinical trials in 2008. The clinical endpoints for both of these trials will be a reduction in pelvic pain associated with endometriosis, utilizing a scale proposed by the FDA. The first Phase II trial will include our selected commercial formulation tablet in two doses, (150 mg and 250 mg); this trial was initiated in late 2007 and is expected to enroll approximately 150 patients. The Company expects topline results from the first three months of treatment at the end of 2008 or early 2009. The second trial is a four arm comparator trial of two doses of NBI-56418, placebo or Leuprolide Depot. This trial will be conducted in Central/Eastern Europe and will begin enrollment in the first half of 2008. Topline data from this 3-month double-blind trial should be available in early 2009.

Neurocrine is also investigating the potential of certain GnRH antagonists in treating other hormone-dependent diseases in Men's and Women's Health.

Partnership discussions are ongoing for our GnRH program.

Corticotropin Releasing Factor (CRF1) Receptor Antagonists in Mood Disorders and IBS.

- GSK has recently completed a Phase II "proof of concept" clinical trial in social anxiety disorder (SocAD) with the first CRF antagonist compound, 876008.
- GSK has completed enrollment of patients in a second Phase II "proof of concept" trial with 876008 in irritable bowel syndrome (IBS).
- Additional lead compounds for depression and anxiety include 561679, which has completed a Phase I multi-dose trial, and will be moving into a Phase II depression trial in 2008; and 586529 which has started a Phase I single escalating dose trial.

The CRF collaboration between Neurocrine and GSK has identified multiple unique high affinity and selective antagonists for the CRF1 receptor that are currently in clinical development for mood disorders and IBS. GSK has completed the first Phase II "proof of concept" clinical trial with a lead CRF1 receptor antagonist compound, 876008, for

SocAD and has completed recruiting for a Phase II “proof of concept” clinical trial in IBS.

In the first double-blind, randomized, placebo controlled, multiple dose study to evaluate the safety and efficacy of the CRF1 receptor antagonist compound in patients with SocAD no statistically significant differences were observed in the key efficacy endpoints between 876008 and placebo at 12 weeks. This study included more than 200 adult subjects and assessed efficacy, safety, tolerability and pharmacokinetics of the compound and the drug was generally well tolerated with no serious adverse events reported.

The second “proof of concept” trial is a Phase II double-blind, randomized, placebo controlled study to evaluate the safety and efficacy of 876008 in patients with IBS. Approximately 130 patients meeting established diagnostic criteria for IBS have been entered into this cross-over design trial. Standard assessments of safety, tolerability and pharmacokinetics will be conducted. The clinical endpoints reflect change in symptom frequency and severity via validated scales for IBS and the data should be available in the second half of 2008.

GSK is advancing the second lead CRF1 receptor antagonist, 561679, into a Phase II depression study later this year. GSK has also initiated a Phase I single dose escalating clinical trial with 586529, an additional CRF1 receptor antagonist compound.

Additional Programs:

Urocortin 2 for congestive heart failure (CHF):

- Initiation of longer term (up to 72 hours in duration) Phase II clinical trials of urocortin 2 are awaiting additional preclinical data. We have identified a preclinical formulation that allows for the necessary preclinical work to be completed by the third quarter of 2008.

Selective Norepinephrine Reuptake Inhibitor (sNRI) for Neuropathic Pain

- Neurocrine completed a Phase I clinical trial with sNRI for neuropathic pain. The single ascending dose study in healthy volunteers demonstrated that the drug was well tolerated and the pharmacokinetic characteristics were suitable for clinical development. The Company will wait to proceed into multi-dose Phase I clinical trials at this time in order to focus resources on the GnRH program.

Conference Call and Webcast Today at 5:00 PM 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 1-800-862-9098, (US) or 785-424-1051 (International) using the conference ID: 7NBIX2. 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 1-800-723-0520 (US) or 402-220-2653 (International) using the conference ID: 7NBIX2. The call will be archived for two weeks.

Neurocrine Biosciences, Inc. is a 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, anxiety, depression, irritable bowel syndrome, endometriosis and CNS related disorders. Indiplon was licensed from DOV Pharmaceuticals in 1998. 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 indiplon program, GnRH program, R & D pipeline and Company overall. Specifically, the risks and uncertainties the Company faces with respect to its indiplon program include, but are not limited to; risk that the Company will not be able to address issues and or requests set forth in the December 12, 2007 indiplon capsule action letter from the FDA in a timely manner if at all; risk that the Company will not be able to address issues and or requests set forth in the December 12, 2007 indiplon capsule action letter from the FDA in a manner acceptable to the FDA if at all; the risk that FDA may reject any future indiplon regulatory filings or find them incomplete or insufficient; and risk that indiplon approval and subsequent commercialization may be significantly or indefinitely delayed or never accomplished. The Company also

faces risks and uncertainties with respect to the Company's GnRH program including risk that the Company's GnRH clinical trials will fail to demonstrate that the Company's clinical candidates are safe and effective; risk that the Company's GnRH clinical candidates will not proceed to later stage clinical trials; risks associated with the Company's dependence on corporate collaborators for development, commercial manufacturing and marketing and sales activities. In addition, the Company faces risks and uncertainties with respect to the Company's R & D pipeline including risk that the Company's research stage GnRH receptor antagonists, urocortin 2, CRF1 receptor antagonist, and sNRI clinical candidates will not proceed to later stage clinical trials, 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, 2006 and Form 10-Q for the quarter ended September 30, 2007. 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 per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2007	2006	2007	2006
	(unaudited)		(unaudited)	
Revenues:				
Sponsored research and development	\$ 19	\$ 213	\$ 139	\$ 6,716
License fees and milestones	486	9,227	986	16,038
Sales force allowance	—	—	—	16,480
Grant Revenue	27	—	99	—
Total revenues	<u>532</u>	<u>9,440</u>	<u>1,224</u>	<u>39,234</u>
Operating expenses:				
Research and development	24,340	18,608	81,985	97,678
Sales, general and administrative	10,786	7,095	37,481	54,873
Prepaid Royalty Write-Off	94,000	—	94,000	—
Total operating expenses	<u>129,126</u>	<u>25,703</u>	<u>213,466</u>	<u>152,551</u>
Loss from operations	(128,594)	(16,263)	(212,242)	(113,317)
Other income and (expenses):				
Interest income and expense, net	616	1,543	4,814	6,576
Other income and (expense), net	3	8	129	(464)
Total other income	<u>619</u>	<u>1,551</u>	<u>4,943</u>	<u>6,112</u>
Net loss	<u><u>\$ (127,975)</u></u>	<u><u>\$ (14,712)</u></u>	<u><u>\$ (207,299)</u></u>	<u><u>\$ (107,205)</u></u>
Net loss per common share:				
Basic and diluted	\$ (3.35)	\$ (0.39)	\$ (5.45)	\$ (2.84)
Shares used in the calculation of net loss per common share:				
Basic and diluted	38,165	37,894	38,009	37,722

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2007 <small>(unaudited)</small>	December 31, 2006
Cash, cash equivalents and marketable securities	\$ 179,385	\$ 182,604
Other current assets	3,563	11,054
Total current assets	182,948	193,658
Property and equipment, net	82,598	91,378
Prepaid royalty	—	94,000
Other non-current assets	11,108	10,641
Total assets	\$ 276,654	\$ 389,677
Current liabilities	\$ 29,907	\$ 20,116
Long-term liabilities	128,050	54,845
Stockholders' equity	118,697	314,716
Total liabilities and stockholders' equity	\$ 276,654	\$ 389,677