



**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**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 3, 2009**

**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.)

**12780 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))
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## **TABLE OF CONTENTS**

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

[ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.](#)

[SIGNATURES](#)

[EXHIBIT INDEX](#)

[EX-99.1](#)

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[Table of Contents](#)

**ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.**

On February 3, 2009, Neurocrine Biosciences, Inc. announced its financial results for the fourth quarter and year ended December 31, 2008. 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.

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
99.1	Press Release dated February 3, 2009

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**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 3, 2009

NEUROCRINE BIOSCIENCES, INC.

/s/ TIMOTHY P. COUGHLIN

Timothy P. Coughlin

Vice President and Chief Financial Officer

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**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	Press Release dated February 3, 2009

**FOR IMMEDIATE RELEASE**

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

**NEUROCRINE BIOSCIENCES REPORTS FOURTH QUARTER  
AND YEAR-END 2008 RESULTS**

SAN DIEGO, Feb. 3, 2009 — Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the fourth quarter and year ended December 31, 2008. For the three months ended December 31, 2008, the Company reported a net loss of \$28.9 million or \$0.75 loss per share compared to a net loss of \$128.0 million or \$3.35 loss per share for the same period last year. For the year ended December 31, 2008, the Company had a net loss of \$88.6 million or \$2.30 loss per share compared to a net loss of \$207.3 million or \$5.45 loss per share in 2007. The decrease in net loss is primarily the result of a one-time write down in 2007 of \$94.0 million for asset impairment related to a prepaid royalty, coupled with the fourth quarter of 2007 restructuring and ongoing cost control measures throughout 2008.

Revenues for the fourth quarter of 2008 were \$0.7 million compared with \$0.5 million for the same period last year. Revenues for the year ended December 31, 2008, were \$4.0 million, compared with \$1.2 million for 2007. The increase in revenues for the year ended December 31, 2008 is primarily due to revenue recognized under the Dainippon Sumitomo Pharma Co. Ltd. (DSP) collaboration agreement. The Company recognized \$2.9 million and \$0.5 million in license fee revenue from DSP during 2008 and 2007, respectively.

Research and development expenses were \$11.9 million in the fourth quarter of 2008 compared to \$24.3 million for the fourth quarter of 2007. For the year ended December 31, 2008, research and development expenses were \$55.3 million compared to \$82.0 million last year. The decrease in quarterly and year-to-date research and development expenses is primarily due to cost savings arising from our restructuring during the fourth quarter of 2007, and ongoing cost control measures throughout 2008.

Sales, general and administrative expenses were \$3.8 million for the fourth quarter 2008 compared with \$10.8 million for the same period in 2007. For the year ended December 31, 2008 sales, general and administrative expenditures totaled \$20.2 million compared to \$37.5 million in 2007. The decrease in quarterly and year-to-date sales, general and administrative expenses is primarily due to cost savings arising from our restructuring during the fourth quarter of 2007, and ongoing cost control measures throughout 2008.

During the fourth quarter of 2008, the Company amended the lease agreement for its two building campus. Under the amendment, the Company vacated the front office building and established a mechanism for the Company to reduce its fixed costs related to the front office building. As a result of vacating the front office building, the Company incurred a "cease-use" expense of \$15.7 million in the fourth quarter of 2008.

Additionally, the Company terminated its option to repurchase the buildings at a predetermined inflationary cost. The forfeiture of this repurchase option resulted in the Company removing a \$108.7 million liability from its balance sheet, \$69.6 million of real estate related assets, and establishing a non-cash liability "deferred gain on sale of real estate" of \$39.1 million, of which \$3.5 million was recognized as other income during the fourth quarter of 2008, the balance of which will be recognized over the remaining term of the lease.

The Company's balance sheet at December 31, 2008 reflected total assets of \$118.2 million including cash and investments of \$101.5 million, and no long-term debt.

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“During 2008, we performed to plan from both a scientific and financial standpoint. We completed the GnRH 603 study with outstanding statistically and clinically significant results. Additionally, both the 702 and 703 studies in GnRH were initiated and are on track. The preclinical work for urocortin 2 was successfully completed, and we advanced another compound, a VMAT2 inhibitor, now ready for clinical development. We pushed all these initiatives forward while meeting our main financial goal to end 2008 with over \$100 million in cash and investments,” said Kevin C. Gorman, President and CEO of Neurocrine Biosciences.

## **2009 Financial Guidance**

Exclusive of any new partnering agreements, the Company expects to have a cash burn in 2009 of approximately \$50 to \$55 million. This projected burn includes all the activities necessary for completion of the Phase II program for elagolix and requesting the end of Phase II meeting with the FDA in the fourth quarter of 2009.

## ***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 to meet the Company-wide goal of bringing one new compound into development each year.

## **GnRH Antagonists in Expanded Phase II Clinical Trials for Endometriosis**

### **Elagolix for Endometriosis**

During 2008, the Company announced the positive safety and efficacy results from the completed 6-month treatment phase of its Phase IIb clinical trial (PETAL Study) using its proprietary, orally-active nonpeptide Gonadotropin-Releasing Hormone (GnRH) receptor antagonist, elagolix.

The primary endpoint, percent change from baseline in mean bone mineral density (BMD) demonstrated elagolix did not induce significant bone loss over the six month treatment period. Additionally, elagolix also met the secondary endpoints of improvement in endometriosis symptoms using several different scales for endometriosis pain. The 6-month results from this study, together with data from the other Phase II studies, will be the basis for securing agreement on a registration plan with the Food and Drug Administration (FDA).

The Company is also currently conducting two additional randomized placebo-controlled Phase IIb clinical trials. The primary clinical endpoint for both of these trials is a reduction in pelvic pain associated with endometriosis, utilizing a Numeric Rating Scale. The first Phase IIb trial includes the Company’s selected commercial formulation tablet in two once daily doses, (150 mg and 250 mg); this trial has completed the initial three-month placebo controlled dosing regimen and continues with an additional three-months of elagolix treatment. The Company will report top-line results from the first three months of treatment at the end of the first quarter of 2009. The second trial is a four arm comparator trial of two once daily doses of elagolix (150 mg and 250 mg), placebo or leuprolide depot. This trial is being conducted in Central Eastern Europe and is currently enrolling. Top-line data from this 3-month double-blind trial of approximately 180 patients is expected to be available in the third quarter of 2009.

The Company expects to hold an end of Phase II meeting with the FDA in late 2009.

Neurocrine is also investigating the potential of certain GnRH antagonists in treating other hormone-dependent diseases in men’s and women’s health.

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### **Corticotropin Releasing Factor (CRF1) Receptor Antagonists for Anxiety/Depression and IBS**

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 irritable bowel syndrome (IBS).

In a double-blind, randomized, placebo controlled, multiple dose study to evaluate the safety and efficacy of the CRF1 receptor antagonist, 876008, in approximately 130 patients with IBS, no statistically significant differences were observed in the key efficacy endpoints between 876008 and placebo.

GSK has advanced a novel lead CRF1 receptor antagonist compound, 561679, into a Phase II trial in patients with major depressive disorder. Enrollment of approximately 150 subjects is anticipated in this 6-week randomized, double-blind, placebo-controlled trial.

In addition to the two compounds listed above, GSK has also successfully completed a Phase I single dose-escalating clinical trial with a third CRF1 compound, 586529, for the treatment of anxiety and depression.

### **Urocortin 2 for Congestive Heart Failure (CHF) Completes Preclinical Evaluations**

In December 2008 the Company completed two preclinical studies for urocortin 2 with favorable outcomes. The two GLP toxicology and safety assessment studies, over 14 days of continuous infusion, were completed in distinct species models, and confirmed the results of the two previous non-GLP studies. The favorable results of these studies should allow urocortin 2 to be infused for periods up to two weeks in duration in humans.

### **Vesicular Monoamine Transporter 2 Inhibitor (VMAT2)**

VMAT2 is a protein concentrated in the human brain that is essential for the transmission of nerve impulses between neurons. The Company has identified a highly selective VMAT2 inhibitor that is effective in regulating the levels of dopamine release during nerve communication, while at the same time having minimal impact on the other monoamines thereby reducing the likelihood of "off target" side effects. This clinical candidate should be effective in the management of hyperkinetic movement disorders characterized by involuntary bodily movements as seen in patients suffering from Tardive Dyskinesia, and Huntington's disease. Additionally, the modulation of dopamine pathways may also be useful for patients suffering from schizophrenia.

### **Indiplon Update**

The Company met with the FDA in July for an end of review meeting related to the December 12, 2007 approvable letter for indiplon capsules. The FDA meeting focused on the three additional requirements outlined in the approvable letter. After exchange of correspondence regarding meeting minutes, the Company continues to await the FDA's final version of these minutes to determine the next course of action related to indiplon capsules.

### **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 1-800-895-0198 (US) or 785-424-1053 (International) using the conference ID: 7NEURO. 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 1-800-388-9074 (US) or 402-220-1117 (International) using the conference ID: 7NEURO. The call will be archived for two weeks.

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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 endometriosis, anxiety, depression, pain, diabetes, benign prostatic hyperplasia (BPH), irritable bowel syndrome (IBS) and other neurological and endocrine related diseases and disorders. 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 GnRH program, R & D pipeline and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's GnRH program include risk that the elagolix clinical trials will fail to demonstrate that elagolix is safe and effective; risk that elagolix 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 urocortin 2, CRF1 receptor antagonist, and VMAT2 clinical candidates will not proceed to later stage clinical trials, and risk that the Company's research programs will not identify pre-clinical candidates for further development. The Company also faces risk that the Company may be unable to obtain FDA approval for indiplon commercialization in the near future or at all. 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, 2007 and Form 10-Q for the quarter ended September 30, 2008. 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 per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
	(unaudited)		(unaudited)	
<b>Revenues:</b>				
Sponsored research and development	\$ —	\$ 19	\$ 47	\$ 139
License fees and milestones	729	486	3,919	986
Grant Revenue	—	27	9	99
<b>Total revenues</b>	<b>729</b>	<b>532</b>	<b>3,975</b>	<b>1,224</b>
<b>Operating expenses:</b>				
Research and development	11,885	24,340	55,291	81,985
Sales, general and administrative	3,817	10,786	20,240	37,481
Cease-use expense	15,742	—	15,742	—
Prepaid royalty write-off	—	94,000	—	94,000
<b>Total operating expenses</b>	<b>31,444</b>	<b>129,126</b>	<b>91,273</b>	<b>213,466</b>
Loss from operations	(30,715)	(128,594)	(87,298)	(212,242)
<b>Other income and (expenses):</b>				
Gain on sale of fixed assets	3,494	3	3,578	129
Interest income and expense, net	(1,633)	616	(4,893)	4,814
<b>Total other income</b>	<b>1,861</b>	<b>619</b>	<b>(1,315)</b>	<b>4,943</b>
<b>Net loss</b>	<b><u>\$ (28,854)</u></b>	<b><u>\$ (127,975)</u></b>	<b><u>\$ (88,613)</u></b>	<b><u>\$ (207,299)</u></b>
<b>Net loss per common share:</b>				
Basic and diluted	<u>\$ (0.75)</u>	<u>\$ (3.35)</u>	<u>\$ (2.30)</u>	<u>\$ (5.45)</u>
<b>Shares used in the calculation of net loss per common share:</b>				
Basic and diluted	<u>38,599</u>	<u>38,165</u>	<u>38,449</u>	<u>38,009</u>

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

	December 31, 2008 (unaudited)	December 31, 2007
Cash, cash equivalents and marketable securities	\$ 80,473	\$ 179,385
Other current assets	950	3,563
<b>Total current assets</b>	<b>81,423</b>	<b>182,948</b>
Property and equipment, net	6,191	82,598
Long-term investments	21,057	—
Restricted cash	6,409	6,399
Other non-current assets	3,102	4,709
<b>Total assets</b>	<b><u>\$ 118,182</u></b>	<b><u>\$ 276,654</u></b>
Current liabilities	\$ 26,094	\$ 29,907
Long-term liabilities	55,314	19,305
Leaseback financing obligation	—	108,745
Stockholders' equity	36,774	118,697
<b>Total liabilities and stockholders' equity</b>	<b><u>\$ 118,182</u></b>	<b><u>\$ 276,654</u></b>