# 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): November 1, 2007

# 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:

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

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## ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On November 1, 2007, Neurocrine Biosciences, Inc. announced its financial results for the quarter ended September 30, 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 November 1, 2007	

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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: November 1, 2007 NEUROCRINE BIOSCIENCES, INC.

/s/ TIMOTHY P. COUGHLIN

Timothy P. Coughlin Vice President and Chief Financial Officer

# EXHIBIT INDEX

Exhibit Number 99.1

Description of Exhibit
Press Release dated November 1, 2007

#### FOR IMMEDIATE RELEASE

Contact at Neurocrine Biosciences Elizabeth Foster (858) 617-7600

#### NEUROCRINE BIOSCIENCES REPORTS THIRD QUARTER 2007 RESULTS

San Diego, CA, November 1, 2007 — Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended September 30, 2007. For the third quarter of 2007, the Company reported a net loss of \$27.2 million, or \$0.72 loss per share compared to net loss of \$39.1 million, or \$1.03 loss per share, for the same period in 2006. For the nine months ended September 30, 2007, the Company reported a net loss of \$79.3 million, or \$2.09 loss per share compared to net loss of \$92.5 million, or \$2.46 loss per share, for the same period last year.

Revenues for the third quarter of 2007 were \$0.5 million compared with \$1.1 million for the respective period last year. Revenues for the nine months ended September 30, 2007 were \$0.7 million compared with \$29.8 million for the same period in 2006. The decrease in revenues for the three and nine month periods is primarily due to the cancellation of our collaboration agreement with Pfizer, Inc. (Pfizer). The Company recognized \$0.3 million and \$6.5 million, for the three and nine months ended September 30, 2006 in the form of sponsored development funding under the Pfizer collaboration agreement. License fees, milestones and sales force allowance recognized for the three and nine months ended September 30, 2006 were \$0.7 million and \$22.3 million, respectively, from Pfizer.

Research and development expenses decreased to \$19.8 million for the third quarter of 2007 from \$25.2 million for the respective period in 2006. For the nine months ended September 30, 2007 and 2006, research and development expenses were \$57.6 million and \$79.1 million, respectively. This decrease in research and development expenses primarily resulted from our severance program in 2006.

Sales, general and administrative expenses decreased to \$9.6 million for the third quarter of 2007 compared with \$16.1 million during the same period last year. For the nine months ended September 30, 2007, sales, general and administrative expenses were \$26.7 million compared to \$47.8 million for the respective period in 2006. This decrease in sales, general and administrative expenses is a result of our severance program in 2006.

The Company's balance sheet on September 30, 2007 reflected total assets of \$317.5 million, including cash, cash equivalents, and marketable securities of \$124.8 million as compared with balances at December 31, 2006 of \$389.7 million and \$182.6 million, respectively.

Neurocrine today announced that it has entered into an exclusive licensing agreement for the development and commercialization of *indiplon* in Japan with Dainippon Sumitomo Pharma Co, Ltd. (DSP). Under the terms of the agreement, Neurocrine will receive an initial payment of \$20 million and an additional \$10 million payment upon FDA approval for *indiplon*. Neurocrine is eligible to receive additional milestone payments associated with the successful development and commercialization of *indiplon* in Japan. Upon commercialization of *indiplon*, Neurocrine will also receive royalties from DSP on sales in Japan.

The Company also announced today that it has entered into a sale and leaseback agreement with Veralliance Properties for its real estate assets, with an expected closing date before year-end 2007. Total consideration to be received by Neurocrine for the properties is \$108 million. Concurrently with the closing of the transaction, Neurocrine will lease back its corporate headquarters under a lease with a 10 year term. Neurocrine has certain options to repurchase all of the properties included in the transaction during the term of the lease. Under the terms of the asset purchase agreement, Neurocrine anticipates that it will receive cash of approximately \$60 million net of fees, expenses and existing indebtedness.

"We are encouraged by the continued progress of our product candidates advancing through development this past quarter, lead by our GnRH and CRF programs. In anticipation of our PDUFA date on December 12, 2007 we are currently engaged in pre-commercialization activities for *indiplon*. We are pleased to announce our licensing agreement with Dainippon Sumitomo, one of the leading multi-national pharmaceutical companies in Japan, to develop and commercialize *indiplon* in this rapidly growing market. We are currently in discussions with multiple pharmaceutical companies for *indiplon* commercialization rights in North America as well as a North American or worldwide GnRH collaboration, and are working to conclude these by year-end," said Gary A. Lyons, President and CEO of Neurocrine Biosciences.

"Throughout 2007, we have maintained a well-controlled burn rate. The closing of our sale and leaseback transaction coupled with the signing of our licensing agreement with Dainippon Sumitomo will provide approximately \$80 million in cash to Neurocrine replenishing our projected year-end cash balances to near beginning of the year levels," said Timothy P. Coughlin, Vice President and Chief Financial Officer of Neurocrine Biosciences.

#### **Indiplon:**

In the third quarter, the Company announced that it has received notification that the U.S. Food and Drug Administration (FDA) has accepted the Company's resubmission of its New Drug Application (NDA) for *indiplon* 5 mg and 10 mg for the treatment of insomnia and has set a PDUFA action date of December 12, 2007.

Neurocrine believes that *indiplon*'s profile may offer an effective solution for those patients who suffer from insomnia. The Company initiated an exploratory Phase IIIb single-blind study to assess various measures of next-day functioning in adult primary insomnia patients following the administration of *indiplon* in response to a bothersome nocturnal awakening. Enrollment is expected to be completed at the end of the 4th Quarter, 2007.

#### **Indiplon and Insomnia-related Peer Review Publications**

This year is an important year for insomnia related medical education. Neurocrine recently presented abstracts at the 5th World Congress of the World Federation of Sleep Research and Sleep Medicine Societies. Additionally, at the meeting new epidemiology data from Stanford University was presented indicating that nocturnal awakenings and difficulty returning to sleep are common, bothersome and associated with significant next-day impairment. The journal *SLEEP* has accepted a manuscript reporting the efficacy and safety of *indiplon* when used as needed for middle-of-the-night awakenings and publication is anticipated in December 2007. Neurocrine plans to submit additional *indiplon* clinical manuscripts in key scientific journals in 2007 and 2008.

#### **Pipeline Highlights**

Neurocrine's clinical development group and corporate partners are advancing our lead programs through development. Neurocrine scientists continue to build up Neurocrine'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**

- Enrollment of patients in the 6-month Phase IIb clinical trial with NBI-56418 is on track for randomization of the last subject expected during the 4th Ouarter. 2007.
- An additional Phase IIb clinical trial with the new formulation tablet is anticipated to begin in early 1st Quarter 2008 utilizing clinical endpoints that incorporate recent guidance from the FDA.

Neurocrine is on track for enrollment of the last patient in a Phase IIb study in which 240 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. 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. Enrollment is expected to be completed during the fourth quarter 2007. 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 new tablet formulation has been selected based upon optimal manufacturing processes and tablet characteristics and will be used in all future studies.

Following the success of GnRH compound NBI-56418 currently in Phase II clinical development, Neurocrine is also investigating the potential of certain GnRH antagonists in treating other hormone-dependent diseases in Men's and Women's Health.

#### Corticotropin Releasing Factor (CRF1) Receptor Antagonists in Two Proof of Concept Phase II Trials for Anxiety/Depression and IBS

- GSK has completed enrollment of patients with lead compound, 876008, in one Phase II "proof of concept" clinical trial in social anxiety disorder (SocAD) with reporting of data expected toward the end of 2007.
- GSK also continues to enroll patients in a second Phase II "proof of concept" trial with 876008 in irritable bowel syndrome (IBS).
- An additional lead compound, 561679, for depression and anxiety has completed a Phase I multi-dose trial.

The CRF collaboration between Neurocrine and GlaxoSmithKline (GSK) has identified multiple unique high affinity and selective antagonists for the CRF1 receptor that are currently in clinical development for anxiety-related disorders and irritable bowel syndrome (IBS). GSK is conducting two Phase II "proof of concept" clinical trials with a lead CRF1 receptor antagonist compound, 876008, for two indications, social anxiety disorder (SocAD) and IBS. Data from the clinical trial in SocAD is expected to be reported at the end of 2007.

The first "proof of concept" trial is a Phase II double-blind, randomized, placebo controlled, multiple dose study to evaluate the safety and efficacy of the CRF1 receptor antagonist compound in patients

with SocAD. The four-arm study will include more than 200 adult subjects with Generalized Social Anxiety Disorder/Social Phobia. Efficacy, safety, tolerability and pharmacokinetics will be assessed. The clinical endpoints of the study include validated scales for assessment of anxiety disorders including the Liebowitz Social Anxiety Scale and the Social Avoidance and Distress Scale.

The second "proof of concept" trial is a Phase II double-blind, randomized, placebo controlled study to evaluate the safety and efficacy of this compound in patients with IBS. Approximately 130 patients meeting established diagnostic criteria for IBS will be 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.

GSK also advanced an additional lead CRF1 receptor antagonist, 561679, in depression and anxiety for which a Phase I multi-dose study has been completed.

#### **Additional Programs:**

#### **Urocortin 2 for congestive heart failure (CHF):**

• Initiation of additional Phase II trials of urocortin 2 are awaiting additional preclinical data. We are currently evaluating new formulations to complete our preclinical program to further advance urocortin 2 into additional Phase II clinical studies.

# Valnoctamide Stereoisomers for Neurological and Psychiatric Diseases

Neurocrine expects to file an IND for one of the stereoisomers of valnoctamide and initiate clinical development in 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 its resources on *indiplon* and GnRH.

#### **A2A Receptor Antagonists**

- Neurocrine is currently reviewing a number of adenosine A2A receptor antagonists in preclinical studies. These evaluations may also help to guide the preclinical selection of drug candidates in which both symptom relief and neuroprotective actions have been optimized.
- Neurocrine is collaborating with the Cure Huntington's Disease Initiative (CHDI) to investigate the neuroprotective effects of A2A antagonists in a preclinical model of Huntington's Disease, and with the Michael J. Fox Foundation (MJFF) to evaluate the neuroprotective effects of A2A antagonists in preclinical models of Parkinson's disease, to assess their potential to modify early disease progression.

#### 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 1-800-894-5910, (US) or 785-424-1052 (International) using the conference ID: 7NBIX. The call can also be accessed via the webcast through the Company's website at <a href="http://www.neurocrine.com">http://www.neurocrine.com</a>

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 1-800-727-5306 (US) or 402-220-2670 (International) using the conference ID: 7NBIX. 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 <a href="http://www.neurocrine.com">http://www.neurocrine.com</a>

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 and R & D pipeline. Specifically, the risks and uncertainties associated with the Company's indiplon program and planned commercialization activities, including but not limited to; risk that regulatory authorities may find our resubmission of the indiplon capsule NDA incomplete or insufficient or otherwise unapprovable or that approval may be delayed; risk that following approval of indiplon capsules, commercialization may be delayed for any of a number of reasons including market conditions and product supply; risk that we will not be able to independently commercialize indiplon capsules or find a marketing partner on reasonable terms or at all; risk that the indiplon capsule labeling granted by regulatory authorities may limit the commercial success of indiplon capsules; and risk relating to market acceptance of indiplon capsules following marketing approval. In addition, the Company faces risks and uncertainties with respect to the Company's R & D pipeline including risk that the Company's GnRH receptor antagonist, urocortin 2, CRF1 receptor antagonist, and sNRI clinical candidates will not proceed to later stage clinical trials, risk that the Company's valnoctamide stereoisomers, adenosine A2A receptor antagonist preclinical candidates will not advance to clinical trials; risk that the Company's glucose dependent insulin secretagogues and ion channel blocker research programs will not identify pre-clinical candidates for further development; 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; 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, 2006 and Form 10-Q for the quarter ended June 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 September 30, 2007 2006		Nine Months Ended September 30, 	
	2007				
Revenues:	(un	audited)	(una	udited)	
Sponsored research and development	\$ 13	\$ 348	\$ 120	\$ 6,503	
License fees and milestones	500	726	500	6,811	
Sales force allowance	_	_	_	16,480	
Grant Revenue	27	_	72	_	
Total revenues	540	1,074	692	29,794	
Operating expenses:					
Research and development	19,795	25,223	57,645	79,070	
Sales, general and administrative	9,571	16,047	26,695	47,778	
Total operating expenses	29,366	41,270	84,340	126,848	
Loss from operations	(28,826)	(40,196)	(83,648)	(97,054)	
Other income and (expenses):					
Interest income and expense, net	1,583	1,525	4,198	5,033	
Other income and (expense), net	3	(472)	126	(472)	
Total other income	1,586	1,053	4,324	4,561	
Net loss	<u>\$ (27,240)</u>	\$(39,143)	<u>\$ (79,324)</u>	<u>\$ (92,493)</u>	
Net loss per common share:					
Basic and diluted	\$ (0.72)	\$ (1.03)	\$ (2.09)	\$ (2.46)	
Shares used in the calculation of net loss per common share:					
Basic and diluted	37,990	37,868	37,956	37,664	
Condensed Cons	BIOSCIENCES, INC. olidated Balance Sheets thousands)				
			September 30, 2007	December 31, 2006	
Cash, cash equivalents and marketable securities			(unaudited) \$ 124,833	\$ 182,604	
Other current assets			3,347	11,054	
Total current assets			128,180	193,658	
Property and equipment, net			84,631	91,378	
Prepaid royalty			94,000	94,000	
Other non-current assets			10,687	10,641	
Total assets			\$ 317,498	\$ 389,677	
Current liabilities			\$ 20,021	\$ 20,116	
Long-term liabilities			52,523	54,845	
Stockholders' equity			244,954	314,716	
Total liabilities and stockholders' equity			\$ 317,498	\$ 389,677	