# 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): October 28, 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)
- 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))

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

On October 28, 2009, Neurocrine Biosciences, Inc. announced its financial results for the quarter ended September 30, 2009. 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 October 28, 2009

## **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.

NEUROCRINE BIOSCIENCES, INC.

Dated: October 28, 2009

/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 October 28, 2009

#### FOR IMMEDIATE RELEASE

Contact at Neurocrine Biosciences Investor Relations (858) 617-7600

#### NEUROCRINE BIOSCIENCES REPORTS THIRD QUARTER 2009 RESULTS

San Diego, CA, October 28, 2009- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended September 30, 2009. For the third quarter of 2009, the Company reported a net loss of \$8.2 million, or \$0.21 per share, compared with a net loss of \$17.7 million, or \$0.46 per share, for the same period in 2008. For the nine months ended September 30, 2009, the Company reported a net loss of \$43.1 million, or \$1.11 per share, as compared to \$59.8 million, or \$1.56 per share, for the same period last year.

Revenues for the third quarter of 2009 were \$0.7 million, compared with \$0.8 million for the same period last year. Revenues for the nine months ended September 30, 2009 were \$2.2 million, compared with \$3.2 million for the same period in 2008. The decrease in revenues is primarily due to milestones recognized in 2008 under our collaboration agreement with GlaxoSmithKline related to the clinical advancements of our CRF program. During both nine month periods ending September 30, 2009 and 2008, we recognized \$2.2 million in revenue under our collaboration agreement for indiplon with Dainippon Sumitomo Pharma Co. Ltd. from amortization of up-front licensing fees.

Research and development expenses decreased to \$7.4 million during the third quarter of 2009 compared with \$13.0 million for the same period in 2008. For the nine months ended September 30, 2009, research and development expenses were \$29.1 million, compared to \$43.4 million for the same period last year. The decrease in research and development expenses is primarily due to cost savings from our recent restructuring and decreasing external clinical development expenses related to the elagolix program. Personnel costs decreased in the first nine months of 2009 by \$3.0 million compared with the first nine months of 2008 and external development spending decreased by \$8.3 million for the same period.

General and administrative expenses were \$3.0 million for the third quarter of 2009 and \$3.5 million during the same period last year. For the nine months ended September 30, 2009, general and administrative expenses were \$12.0 million, compared to \$16.4 million for the same period in 2008. Personnel expenses decreased by \$3.0 million in the first nine months of 2009 compared to the first nine months of 2008 primarily as a result of our restructuring program in the second quarter of 2009. Additionally, other non-personnel cost reductions have resulted in savings of approximately \$1.2 million in the nine month period ending September 30, 2009 compared with the same period in the prior year.

The Company's balance sheet on September 30, 2009 reflected total assets of \$75.9 million, including cash and investments of \$63.7 million compared with balances at December 31, 2008 of \$118.2 million and \$101.5 million, respectively.

"We have made tremendous progress in our lead programs this past quarter," said Kevin C. Gorman, President and Chief Executive Officer. "After a very productive Type C meeting with the FDA, we rapidly launched our Daisy Petal study which is enrolling well. In addition, we've moved our VMAT-2 program into the clinic to determine if the ideal pharmacokinetic profile we have seen in animal models is achieved in humans."

#### **Pipeline Highlights**

#### **Elagolix Update**

The Company held a Type C meeting with the Food and Drug Administration (FDA) in August to discuss the non-menstrual pelvic pain scale proposed by the FDA and used in the Lilac Petal Study (0702). Based on this meeting, the Company modified the wording of the non-menstrual pain daily scale and launched a new clinical trial, the Daisy Petal Study (0901). This double-blind placebo-controlled clinical trial is designed to provide an assessment of this modified scale over a two month treatment period of 150 mg elagolix, followed by twenty weeks of open-label treatment.

The blinded baseline data from the initial subjects screened for the Daisy Petal Study (0901) indicate that the modified daily non-menstrual pain scale reflects a wider dynamic range of pain scores which was lacking in the previous daily non-menstrual pelvic pain scale. This should allow for detection of treatment difference between elagolix and placebo for non-menstrual pain in the study population. The mean baseline score using the previous scale in the Lilac Petal Study (0702) was 0.83 (using the 0-3 scale on non-menstrual days), while preliminary Daisy Petal Study (0901) data with the new scale demonstrate a mean baseline score of approximately 1.5 (using the 0-3 scale on non-menstrual days), in the initial group of subjects recruited. Encouraged by the wider dynamic range of this modified scale, the Company has proposed a modest increase in the number of subjects for enrollment. This essentially moves the trial from a directional characterization of the endpoint (i.e., to estimate sample size for a Phase III trial) to a trial powered to provide statistical significance of the new non-menstrual pain endpoint versus placebo. The Company expects top-line data from the Daisy Petal Study (0901) in the second quarter of 2010.

"We are pleased with the outcome of the Type C meeting with the FDA," said Chris O'Brien, Chief Medical Officer. "Given the dynamic range of the daily non-menstrual pain endpoint in our baseline assessments, we were able to quickly estimate the appropriate sample size needed to assess this endpoint for statistical significance, and made the decision to increase our patient population accordingly."

The Tulip Petal Study (0703) has completed subject randomization (n=174) and treatment through Week 12 in Central Eastern Europe. This study is designed as a randomized, double-blind, placebo and active controlled trial with four treatment arms; elagolix 150 mg, elagolix 250 mg, leuprolide depot, and placebo. We expect top-line data based on the first three months of placebo and active controlled treatment to be available later in the fourth quarter.

An abstract providing Petal Study (0603) clinical efficacy and safety data was presented at the American Society for Reproductive Medicine in Atlanta, on October 21, 2009.

#### **Urocortin 2 Update**

The Christchurch Cardioendocrine Research Group at University of Otago, Christchurch School of Medicine and Health Sciences, New Zealand, in collaboration with Neurocrine, has obtained regulatory approval to begin a pilot study in patients with Acute Decompensated Heart Failure. These patients are the target population for the Urocortin 2 mechanism of action and the investigational intervention will be compared to standard-of-care treatment; enrollment of 50 subjects is underway.

#### VMAT2 Update

The highly selective blockade of the Vesicular Monoamine Transporter 2 (VMAT2) with NBI-98854 should be of clinical benefit in patients with a variety of CNS diseases, especially those with involuntary hyperkinetic movement disorders such as Tardive Dyskinesia. During August 2009, we initiated a single ascending dose Phase 1 study in Canada. Pending successful completion and evaluation of this initial Phase I study, we expect to launch a second Phase I study assessing multiple repeated doses of NBI-98854 in early 2010.

#### Conference Call and Webcast Thursday, October 29, 2009 at 8:30a.m. EDT

Neurocrine will hold a live conference call and webcast tomorrow morning, Thursday, October 29, 2009 at 8:30 a.m. Eastern Daylight Time (5:30 a.m. Pacific Daylight Time). Participants can access the live conference call by dialing 1-800-894-5910 (US) or 785-424-1052 (International) using the conference passcode 7NEURO. 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 1-800-723-2156 (US) or 402-220-2660 (International) using the passcode 7NEURO. 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 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 <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 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; and 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, 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. 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, 2008 and Form 10-Q for the quarter ended June 30, 2009. 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 loss per share data)

	Three Mont Septemb	per 30,	Nine Months Ended September 30,		
	<u>2009</u> (unaud	2008 lited)	<u>2009</u> (unaud	2008 lited)	
Revenues:	(unuu		(	ilicu)	
Sponsored research and development	\$ 3	\$ 32	\$ 23	\$ 48	
License fees and milestones	730	729	2,190	3,189	
Grant revenue				9	
Total revenues	733	761	2,213	3,246	
Operating expenses:	7 401	12.002	20.057	42, 40C	
Research and development General and administrative	7,401 2,966	12,993	29,057	43,406	
Cease use expense	2,966	3,472	11,988 5,858	16,423	
·		16.465		<u></u>	
Total operating expenses	10,456	16,465	46,903	59,829	
Loss from operations	(9,723)	(15,704)	(44,690)	(56,583)	
Other income and (expense):					
Interest income and other income	1,546	(93)	1,568	2,573	
Interest expense	_	(1,914)	_	(5,749)	
Total other income (expense) net	1,546	(2,007)	1,568	(3,176)	
Net loss	<u>\$ (8,177)</u>	<u>\$ (17,711)</u>	\$ (43,122)	\$ (59,759)	
Net loss per common share:					
Basic and diluted	\$ (0.21)	\$ (0.46)	\$ (1.11)	\$ (1.56)	
Shares used in the calculation of net loss per common share:					
Basic and diluted	39,096	38,446	38,938	38,399	

# NEUROCRINE BIOSCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	September 30, 2009 (unaudited)		De	2008 2008
Current assets:				
Cash and investments	\$	57,118	\$	80,473
Other current assets		1,072		950
Total current assets		58,190		81,423
Property and equipment, net		3,395		6,191
Long-term investments		6,602		21,057
Restricted cash		6,322		6,409
Other non-current assets		1,399		3,102
Total assets	\$	75,908	\$	118,182
Current liabilities	\$	24,044	\$	26,094
Long-term liabilities		50,789		55,314
Stockholders' equity		1,075		36,774
Total liabilities and stockholders' equity	\$	75,908	\$	118,182