# 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 6, 2014

# **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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))

Dere-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 February 6, 2014, Neurocrine Biosciences, Inc. announced its financial results for the fourth quarter and year ended December 31, 2013. 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.

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Number	Description of Exhibit
99.1	Press Release dated February 6, 2014

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 6, 2014

NEUROCRINE BIOSCIENCES, INC.

/s/ TIMOTHY P. COUGHLIN

Timothy P. Coughlin Chief Financial Officer

# EXHIBIT INDEX

# Exhibit <u>Number</u> <u>Description of Exhibit</u>

99.1 Press Release dated February 6, 2014

# NEUROCRINE BIOSCIENCES REPORTS FOURTH QUARTER AND YEAR END 2013 RESULTS

#### PROVIDES UPDATE ON RAPIDLY ADVANCING PIPELINE AND FINANCIAL GUIDANCE FOR 2014

San Diego, CA, February 6, 2014—Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter and year ended December 31, 2013.

For the fourth quarter of 2013, the Company reported a net loss of \$10.6 million, or \$0.16 loss per share, compared to net income of \$9.5 million, or income of \$0.14 per fully diluted share, for the same period in 2012. For the year ended December 31, 2013, the Company reported a net loss of \$46.1 million, or \$0.69 loss per share, as compared to net income of \$5.0 million, or income of \$0.08 per fully diluted share, for 2012. The change in operating results from 2012 to 2013 is due to the successful completion of the sponsored research and development phases of the Company's license agreements with both AbbVie and Boehringer Ingelheim during 2012, as scheduled.

The Company's balance sheet at December 31, 2013 reflected total assets of \$154.7 million, including cash, investments and receivables of \$146.8 million compared with balances at December 31, 2012 of \$196.0 million and \$188.3 million, respectively.

"During the last twelve months we have made great progress across our clinical pipeline. Our VMAT2 program has recently successfully completed Phase II and we are now looking forward to an End-of-Phase II meeting with the FDA, while our partner AbbVie initiated the second of two Phase III trials of elagolix in endometriosis as well as a Phase IIb uterine fibroids study," said Kevin C. Gorman, President and CEO of Neurocrine Biosciences. "Looking forward to 2014 we see another year of significant growth with important data points for our two lead clinical programs as well as several promising compounds that have the potential to further strengthen our clinical pipeline."

Revenues for the fourth quarter of 2013 were \$0.7 million, compared to \$21.9 million for the same period in 2012. Revenues for the year ended December 31, 2013 were \$2.9 million, compared with \$53.1 million for the year ended December 31, 2012. The decrease in revenue is due to the successful and timely completion of the sponsored research and development phases of the Company's license agreements during 2012.

Research and development expenses decreased to \$8.9 million during the fourth quarter of 2013, compared with \$9.1 million for the same period in 2012. For the year ended December 31, 2013, research and development expenses were \$39.2 million, compared to \$37.2 million for 2012. The year-over-year increase in research and development expenses was primarily driven by Phase IIb development expenses for the VMAT2 program, coupled with increased compensation related costs, primarily due to share-based compensation.

#### 2014 Financial Guidance

The Company expects to have a net cash burn of approximately \$43 million to \$47 million in 2014. Expenses for 2014 should approximate \$60 million to \$64 million. The anticipated increase in expenses over 2013 levels is primarily due to an increase in research and development efforts as well as higher share-based compensation expense. Net loss for 2014 is expected to be \$56 million to \$61 million, or \$0.82 to \$0.90 loss per share based on 68 million basic shares outstanding. The Company expects to end 2014 with approximately \$100 million in cash, investments and receivables.

#### **Pipeline Highlights**

#### **Elagolix Update**

AbbVie is currently conducting the Violet Petal Study, a Phase III study of elagolix for endometriosis. The study is a 24-week, multinational, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of elagolix in 875 women, age 18 to 49, with moderate to severe endometriosis-associated pain. Approximately 160 sites in the United States, Puerto Rico and Canada are conducting this study.

AbbVie has also initiated the second Phase III study of elagolix for endometriosis. This study is similar in design to the Violet Petal Study and will assess 788 women, age 18 to 49, with moderate to severe endometriosis-associated pain at more than 200 sites globally.

AbbVie is also currently conducting a Phase IIb study of elagolix in uterine fibroids. This study is assessing uterine blood loss in 520 women with heavy uterine bleeding due to uterine fibroids.

#### VMAT2 Update

The Company is utilizing the Kinect and Kinect 2 datasets to compile the End-of-Phase II briefing package along with a proposed Phase III protocol for submission to the FDA in the second quarter of 2014.

The Company also anticipates the End-of-Phase-II meeting for NBI-98854 in tardive dyskinesia to be held with the FDA in the second quarter of 2014. Upon completion of this meeting, the Company anticipates initiating the pivotal Phase III program of NBI-98854 during the second half of 2014.

Additionally, the Company is conducting appropriate preclinical studies to support the advancement of NBI-98854 into clinical trials for individuals suffering from Tourette syndrome, and expects to open the investigational new drug application for Tourette syndrome in 2014.

#### 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 800-862-9098 (US) or 785-424-1051 (International) using the conference ID: NBIX. The call can also be accessed via the webcast through the Company's website at <u>http://www.neurocrine.com</u>.

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 800-723-8184 (US) or 402-220-2668 (International) using the conference ID: NBIX. The call will be archived for two weeks.

Neurocrine Biosciences, Inc. discovers and develops innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through its novel R&D platform, focused on neurological and endocrine based diseases and disorders. The Company's two lead late-stage clinical programs are elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc., and a wholly owned vesicular monoamine transporter 2 inhibitor for the treatment of movement disorders. Neurocrine intends to maintain certain commercial rights to its VMAT2 inhibitor for evolution into a fully-integrated pharmaceutical company.

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 R & D pipeline and the Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's R & D pipeline include risk that elagolix, the company's lead clinical program, will fail to demonstrate that elagolix is safe and effective; risk that elagolix Phase III clinical trials will be delayed for regulatory or other reasons; and risks associated with the Company faces risk that the clinical studies for NBI-98854, the company's VMAT2 inhibitor candidate, will fail to demonstrate that NBI-98854 is safe and effective and risk that NBI-98854 will not proceed to later stage clinical trials. In addition, the Company faces risks and uncertainties with respect to the rest of the Company's R & D pipeline including risk that the Company's clinical candidates will not be found to be safe and effective; and risk that the Company's research programs will not identify pre-clinical candidates for further development. With respect to the Company 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; risk 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; risk 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 annual report on Form 10-K for the year ended December 31, 2012 and quarterly reports on Form 10-Q for the quarters ended March 31, 2013, June 30, 2013 and September 30, 2013. 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 per share data)

(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
Revenues:	2013	2012	2013	2012
Sponsored research and development	\$ —	\$13,959	\$ —	\$18,897
Milestones and license fees	730	7,988	2,919	34,243
Total revenues	730	21,947	2,919	53,140
Operating expenses:	/50	21,047	2,515	55,140
Research and development	8,918	9,097	39,248	37,163
General and administrative	3,342	3,311	13,349	13,437
Cease-use expense		957		1,092
Total operating expenses	12,260	13,365	52,597	51,692
(Loss) income from operations	(11,530)	8,582	(49,678)	1,448
Other income:	( ))	-,	(-))	, -
(Loss) gain on sale/disposal of assets	(1)	7	37	32
Deferred gain on real estate	789	766	3,133	3,042
Investment income, net	85	130	402	489
Other income, net	15	5	16	14
Total other income	888	908	3,588	3,577
Net (loss) income	\$(10,642)	\$ 9,490	\$(46,090)	\$ 5,025
Net (loss) income per common share:	î			
Basic	\$ (0.16)	\$ 0.14	\$ (0.69)	\$ 0.08
Diluted	\$ (0.16)	\$ 0.14	\$ (0.69)	\$ 0.08
Shares used in the calculation of net (loss) income per common share:				
Basic	67,346	66,406	66,989	65,619
Diluted	67,346	67,720	66,989	66,946

# **NEUROCRINE BIOSCIENCES, INC.**

# CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

(unaudited)

	December 31, 2013	December 31, 2012
Cash, cash equivalents and short-term marketable securities	\$ 145,739	\$ 173,013
Other current assets	2,723	16,251
Total current assets	148,462	189,264
Property and equipment, net	1,771	1,900
Long-term investments	—	480
Restricted cash	4,443	4,335
Total assets	\$ 154,676	\$ 195,979
Current liabilities	\$ 11,699	\$ 15,646
Long-term liabilities	22,567	25,961
Stockholders' equity	120,410	154,372
Total liabilities and stockholders' equity	\$ 154,676	\$ 195,979