

Neurocrine Biosciences Reports Fourth Quarter And Year End 2013 Results

Written by Australian Business

SAN DIEGO, Feb. 6, 2014 /PRNewswire/ -- 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
million
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.

\$9.1
for

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

<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 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's dependence on corporate collaborators for Phase III development, commercial manufacturing and marketing and sales activities. Similarly, 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,

2013

2012

2013

2012

Revenues:

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:

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

Neurocrine Biosciences Reports Fourth Quarter And Year End 2013 Results

Written by Australian Business

(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

Neurocrine Biosciences Reports Fourth Quarter And Year End 2013 Results

Written by Australian Business

\$ (46,090)

\$ 5,025

Net (loss) income per common share:

Basic

\$ (0.16)

\$ 0.14

\$ (0.69)

\$ 0.08

Diluted

\$ (0.16)

\$ 0.14

Neurocrine Biosciences Reports Fourth Quarter And Year End 2013 Results

Written by Australian Business

\$ (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

Neurocrine Biosciences Reports Fourth Quarter And Year End 2013 Results

Written by Australian Business

1,900

Long-term investments

-

480

Restricted cash

4,443

4,335

Total assets

\$ 154,676

\$ 195,979

Current liabilities

Neurocrine Biosciences Reports Fourth Quarter And Year End 2013 Results

Written by Australian Business

\$ 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

Neurocrine Biosciences Reports Fourth Quarter And Year End 2013 Results

Written by Australian Business

SOURCE Neurocrine Biosciences, Inc.

RELATED LINKS <http://www.neurocrine.com>