

NEUROCRINE BIOSCIENCES INC

Form 8-K

February 14, 2018

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 14, 2018

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))
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On February 14, 2018, Neurocrine Biosciences, Inc. (the Company) issued a press release announcing that the U.S. Food and Drug Administration (the FDA) has provided guidance on the regulatory path forward to support the New Drug Application (NDA) for opicapone, an investigational drug for Parkinson's disease, after receiving meeting minutes from the January 2018 meeting with the FDA. The FDA has not requested that the Company conduct an additional Phase III study for opicapone prior to the NDA filing. As a result, the Company will proceed with plans to file the NDA for opicapone during the first half of 2019.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 8.01 and Exhibit 99.1 of this Current Report on Form 8-K, 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 (the Securities Act), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Special Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause the Company's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expects, plans, anticipates, believes, estimates, projects, predicts, expressions intended to identify forward-looking statements. These statements reflect the Company's current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent the Company's estimates and assumptions only as of the date of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

| No. | Description |
|------|---|
| 99.1 | <u>Press Release of Neurocrine Biosciences, Inc., dated February 14, 2018</u> |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NEUROCRINE BIOSCIENCES, INC.

Dated: February 14, 2018

By: /s/ Darin M. Lippoldt
Darin M. Lippoldt
Chief Legal Officer