

NEUROCRINE BIOSCIENCES INC
Form 8-K
October 11, 2016

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 earliest event reported): October 10, 2016

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

12780 El Camino Real, San Diego, California

0-22705
(Commission

File Number)

33-0525145
(IRS Employer

Identification No.)

92130

(Address of principal executive offices)

(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))

Item 8.01 Other Events.

On October 10, 2016, Neurocrine Biosciences, Inc. (the *Company*) issued a press release announcing that the U.S. Food and Drug Administration (the *FDA*) has accepted for priority review the New Drug Application (the *NDA*) for INGREZZA™ (valbenazine) for the treatment of tardive dyskinesia. The INGREZZA application has been given a Prescription Drug User Fee Act (PDUFA) target action date of April 11, 2017.

The FDA has not notified the Company of a date for an advisory committee meeting, if any, relating to the NDA.

A Priority Review designation accelerates the FDA review timeline from 10 months to 6 months from the date of acceptance of the NDA. The designation directs the FDA's overall attention and resources to the evaluation of applications for drugs that, if approved, would be a significant improvement in the safety or effectiveness of the treatment of a serious condition. INGREZZA (valbenazine) previously received Fast Track status and Breakthrough Designation status from the FDA.

The NDA for INGREZZA includes the results from the Kinect 2 and Kinect 3 clinical trials which evaluated over 330 tardive dyskinesia patients. Data from these studies along with the results from another 18 clinical trials, extensive preclinical testing and drug manufacturing data were included in the NDA submission.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in the Company's filings with the Securities and Exchange Commission, including without limitation the Company's most recent Quarterly Report on Form 10-Q and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. The Company disclaims any obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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.

Dated: October 10, 2016

NEUROCRINE BIOSCIENCES, INC.

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