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	**0-22705**	**33-0525145**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12780 El Camino Real, San Diego, California	**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))

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", "potential" and similar 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	Press Release of Neurocrine Biosciences, Inc., dated February 14, 2018

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

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Neurocrine Biosciences Will File New Drug Application for Opicapone for Parkinson's Disease Based on Existing Pivotal Clinical Trial Data

Neurocrine Plans to File the NDA During the First Half of 2019

SAN DIEGO, Feb. 14, 2018—Neurocrine Biosciences, Inc. (NASDAQ: NBIX), a biotechnology company focused on neurological and endocrine related disorders, today announced that the U.S. Food and Drug Administration (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. Most importantly, the Neurology Division of the FDA has not requested that Neurocrine conduct an additional Phase III study for opicapone prior to the NDA filing. As a result, Neurocrine will proceed with plans to file the NDA for opicapone during the first half of 2019.

"We had a very productive meeting with the FDA and are pleased that we can proceed with the NDA submission based on the robust clinical data that already exists for opicapone," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine. "We have a tremendous amount of work ahead of us as we compile the FDA-required datasets to prepare for the NDA filing, which we plan to have completed during the first half of 2019. As part of our commitment to helping patients with movement disorders, we are eager to continue advancing this important medicine for the nearly one million patients suffering from Parkinson's disease in the United States."

Opicapone, an investigational drug in the U.S., is a once-daily, peripherally-acting, highly-selective catechol-o-methyltransferase (COMT) inhibitor being developed as an adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors for adult patients with Parkinson's disease and motor fluctuations.

In February 2017, Neurocrine entered into an exclusive licensing agreement with BIAL for the development and commercialization of opicapone in the United States and Canada. Under the terms of the agreement, Neurocrine is responsible for development and commercialization of opicapone in the United States and Canada. As a result of the FDA guidance for the NDA filing, Neurocrine will pay a $10 million milestone payment to BIAL.

About Parkinson's Disease

Parkinson's disease is a chronic and progressive movement disorder that affects approximately one million people in the United States. The disease is characterized by a loss of neurons in the substantia nigra, the area of the brain where dopamine is produced. Dopamine production and synthesis is necessary for coordination and movement. As Parkinson's progresses, dopamine production steadily decreases resulting in tremor, slowed movement (bradykinesia), impaired posture and balance, and speech and writing problems. There is no present cure for Parkinson's disease and management consists of controlling the motor symptoms primarily through administration of levodopa therapies. While this improves the control of Parkinson's symptoms, the disease progresses and the beneficial effects of levodopa begin to wear off, symptoms worsen and patients experience end-of-dose motor fluctuations. These end-of-dose motor fluctuations are improved with the addition of a catechol-o-methyltransferase (COMT) inhibitor to levodopa.

About Opicapone

Opicapone is a novel, once-daily, peripherally-acting, highly-selective catechol-o-methyltransferase (COMT) inhibitor proposed for use as adjunct therapy to levodopa/DOPA decarboxylase inhibitors in Parkinson's patients. Opicapone works by prolonging the duration of effect of levodopa through decreasing its conversion rate into 3-O-methyldopa, thereby reducing the off-time period of Parkinson's and extending the on-time period. A novel compound discovered in the BIAL laboratories, it is designed to provide patients and physicians with a once-daily treatment option without the deleterious side-effects and complicated dosing regimen of other COMT inhibitors.

In June 2016, the European Commission authorized ONGENTYS® (opicapone) as an adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCIs) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilized on those combinations. This European approval was based on data from a clinical development program that included 28 clinical studies of more than 900 patients treated with opicapone in 30 countries worldwide. Opicapone is an investigational drug, not approved for use in the United States or Canada.

The two pivotal Phase III studies utilized for European approval, BIPARK-I and BIPARK-II, demonstrated that opicapone once-daily achieved a statistically significant decrease in off-time periods for Parkinson's patients compared to placebo. The BIPARK-I study was a placebo-controlled study of approximately 600 patients that also included entacapone as an active comparator. The results of this study showed that once-daily opicapone was non-inferior to entacapone dosed multiple times per day. The BIPARK-II study was a placebo-controlled study of approximately 400 patients that also showed a significant decrease in off-time periods for Parkinson's patients. In both studies, opicapone was associated with significant improvements in both patient and clinician global assessments of change. The data from these two Phase III trials also demonstrated that opicapone improved motor fluctuations in levodopa-treated patients regardless of concomitant dopamine agonist or monoamine oxidase type B inhibitors used. Opicapone was generally well tolerated and was not associated with relevant electrocardiographic or hepatic adverse events.

Both of the BIPARK Phase III trials included a one-year open-label extension where opicapone sustained the decrease in off-time and increase in on-time periods that was demonstrated during the double-blind placebo-controlled portion of the studies.

About Neurocrine Biosciences, Inc.

Neurocrine Biosciences is a San Diego based biotechnology company focused on neurologic, psychiatric and endocrine related disorders. The Company markets INGREZZA® (valbenazine) capsules in the United States for the treatment of adults with tardive dyskinesia. INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, and is the first FDA approved product indicated for the treatment of adults with tardive dyskinesia. The Company's three late-stage clinical programs are: elagolix, a gonadotropin-releasing hormone antagonist for

women’s health that is partnered with AbbVie Inc.; opicapone, a novel, once-daily, peripherally-acting, highly-selective catechol-o-methyltransferase inhibitor under investigation as adjunct therapy to levodopa in Parkinson’s patients; and INGREZZA, a novel, once-daily, selective VMAT2 inhibitor under investigation for the treatment of Tourette syndrome.

Neurocrine Biosciences, Inc. news releases are available through the Company’s website at http://www.neurocrine.com.

Forward-Looking Statements

In addition to historical facts, this press release contains 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 opicapone development and commercialization. Specifically, the risks and uncertainties the Company faces include risks that opicapone may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks that opicapone development activities may not be completed on time or at all; risks associated with the Company’s dependence on BIAL for development and manufacturing activities related to opicapone; risks that ongoing or future opicapone clinical trials may not be successful or replicate previous clinical trial results, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding opicapone; risks that opicapone may be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks and uncertainties relating to competitive products and technological changes that may limit demand for opicapone; and other risks described in the Company’s periodic reports filed with the Securities and Exchange Commission, including without limitation the Company’s annual report on Form 10-K for the year ended December 31, 2017. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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