# 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): January 6, 2019**

# 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 2.02 Results of Operations and Financial Condition.**

On January 6, 2019, Neurocrine Biosciences, Inc. (the "Company"), issued a press release announcing preliminary fourth quarter 2018 and full year 2018 net product sales results. The Company's financial statements for the fourth quarter 2018 and full year 2018 have not yet been completed and could result in changes to these preliminary net product sales results. The press release also contained certain 2019 expected milestones related to the Company's products and product candidates. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 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

99.1 Press Release, dated January 6, 2019

**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: January 7, 2019

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

**Exhibit 99.1**

**FOR IMMEDIATE RELEASE**

**Neurocrine Biosciences Provides Preliminary Fourth Quarter and Full-Year 2018 Net Product Sales Results and 2019 Program Milestones**

- *INGREZZA® (valbenazine) Preliminary Fourth Quarter Net Product Sales of Approximately $130 Million with Approximately 22,900 TRx*
- *INGREZZA® (valbenazine) Preliminary Full-Year 2018 Net Product Sales of Approximately $409 Million with Approximately 71,500 TRx*

SAN DIEGO, Jan. 6, 2019 - Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today provided an update on its business performance, including preliminary net product sales results for 2018, and key clinical development programs for 2019. Kevin Gorman, Chief Executive Officer of Neurocrine, will discuss these updates as part of a webcast presentation at the 37th Annual J.P. Morgan Healthcare Conference in San Francisco on Monday, Jan. 7 at 2:30 p.m. PT (5:30 p.m. ET).

"Our fourth quarter and 2018 results reflect the dedication of our team in educating healthcare providers about tardive dyskinesia and the benefit INGREZZA can bring to patients. We still have a lot of work to do as many people suffering from tardive dyskinesia remain undiagnosed and untreated, and we remain committed to helping the lives of patients through our recently expanded field sales team and disease awareness education," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "In 2019, we will remain focused on reaching more patients with INGREZZA and making progress in our clinical development programs, including the planned submission of AbbVie's new drug application for uterine fibroids and our planned submission for Parkinson's disease, as well as advancing our congenital adrenal hyperplasia program."

**Preliminary Fourth Quarter and Full-Year 2018 Net Product Sales Results (Unaudited)**

Based on preliminary unaudited financial information, the Company expects net product sales for the three months and full-year ended December 31, 2018 to be approximately $130 million and $409 million, respectively, compared to $64.5 million and $116.6 million for the same periods in 2017.

**2019 Expected Milestones**

INGREZZA® (valbenazine) for Tardive Dyskinesia

- "Talk About TD" disease state awareness campaign
- Execution of post-marketing clinical studies, including RE-KINECT, the largest real-world study in patients with possible tardive dyskinesia
- Presentations at key scientific annual meetings, including American Academy of Neurology (AAN), American Psychiatric Association (APA), International Parkinson and Movement Disorder Society (MDS)

Elagolix in Collaboration with AbbVie

- Continued launch of ORILISSA® (elagolix) to treat endometriosis by AbbVie
- Elagolix for uterine fibroids: planned 2019 New Drug Application (NDA) submission

Opicapone for Parkinson's Disease

- NDA submission in Q2 2019
- Preparation for 2020 opicapone commercial launch
- Presentations at key scientific annual meetings, including AAN, MDS

Congenital Adrenal Hyperplasia (CAH)/NBI-74788 (In Development)

- Phase IIa data for CAH (adults) in Q1 2019
- Phase IIa initiation for CAH (pediatric) in Q2/Q3 2019
- Pivotal study initiation for CAH (adults) in 2H 2019, pending U.S. Food and Drug Administration (FDA) discussion in Q2

Early Stage Programs

- Investigational New Drug submission and initiation of a Phase I trial for a new, internally discovered program

**About INGREZZA® (valbenazine) Capsules**

INGREZZA, a selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is the first FDA-approved product indicated for the treatment of adults with tardive dyskinesia, a condition associated with uncontrollable, abnormal and repetitive movements of the face, torso, and/or other body parts.

INGREZZA is thought to work by reducing the amount of dopamine released in a region of the brain that controls movement and motor function, helping to regulate nerve signaling in adults with tardive dyskinesia. VMAT2 is a protein in the brain that packages neurotransmitters, such as dopamine, for transport and release in presynaptic neurons. INGREZZA, developed in Neurocrine's laboratories, is novel in that it selectively inhibits VMAT2 with no appreciable binding affinity for VMAT1, dopaminergic (including D2), serotonergic, adrenergic, histaminergic, or muscarinic receptors. Additionally, INGREZZA can be taken for the treatment of tardive dyskinesia as one capsule, once-daily, together with psychiatric medications such as antipsychotics or antidepressants.

**Important Safety Information**

**Contraindications**

INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

**Warnings & Precautions**

**Somnolence**

INGREZZA can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by INGREZZA.

**QT Prolongation**

INGREZZA may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. INGREZZA should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

**Adverse Reactions**

The most common adverse reaction (□5% and twice the rate of placebo) is somnolence. Other adverse reactions (□2% and >placebo) include: anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at **www.fda.gov/medwatch** or call 1-800-FDA-1088.

**Please see INGREZZA full Prescribing Information at www.INGREZZA.com/PI.**

**About Neurocrine Biosciences, Inc.**

Neurocrine Biosciences, a San Diego based biopharmaceutical company, is focused on developing treatments for neurological and endocrine related disorders. The company discovered, developed and markets INGREZZA® (valbenazine) capsules, the first FDA-approved product indicated for the treatment of adults with tardive dyskinesia, an involuntary movement disorder. Discovered and developed through Phase II clinical trials by Neurocrine, ORILISSA® (elagolix), the first FDA-approved oral medication for the management of endometriosis with associated moderate to severe pain in over a decade, is marketed by AbbVie as part of a collaboration to develop and commercialize elagolix for women's health. Neurocrine's clinical development programs include opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in Parkinson's disease patients, elagolix for uterine fibroids with AbbVie, valbenazine for the treatment of Tourette syndrome, and NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH). For more information and the latest updates from Neurocrine Biosciences, please visit 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. These statements include, but are not limited to, statements related to our preliminary financial information, the benefits to be derived from Neurocrine's products and product candidates, including INGREZZA and our partnered product, ORILISSA; the value INGREZZA, ORILISSA, and/or our product candidates may bring to patients; the continued success of the launch of INGREZZA; AbbVie's launch of ORILISSA; and the timing of completion of our clinical, regulatory, and other development activities and those of our collaboration partners. 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 items that may be identified during its financial statement closing process that cause adjustments to the estimates included in this press release; the Company's future financial and operating performance; risks and uncertainties associated with the commercialization of INGREZZA and ORILISSA, including the likelihood of continued revenue and prescription growth of INGREZZA; risks or uncertainties related to the development of the Company's product candidates; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA, ORILISSA, or a product candidate; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA and the Company's product candidates, and the ability of the Company to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding INGREZZA, ORILISSA, or the Company's product candidates; risks associated with the Company's dependence on AbbVie for the commercialization of ORILISSA and the development of elagolix; risks that clinical development activities may not be completed on time or at all; risks that clinical development activities may be delayed for regulatory or other

reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that the benefits of the agreement with BIAL may never be realized; risks associated with the Company's dependence on BIAL for regulatory and manufacturing activities related to opicapone; risks that INGREZZA, ORILISSA, and/or our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2018. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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