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): January 12, 2020

NEUROCRINE BIOSCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**0-22705**	**33-0525145**
(State or Other Jurisdiction of Incorporation)	**(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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value	NBIX	Nasdaq Global Select Market

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 (see General Instructions A.2. below):

☐ 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 12, 2020, Neurocrine Biosciences, Inc. (the "Company"), issued a press release announcing preliminary fourth quarter 2019 and full year 2019 net product sales results. The Company's financial statements for the fourth quarter 2019 and full year 2019 have not yet been completed and could result in changes to these preliminary net product sales results. The press release also contained certain 2020 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.

Exhibit	Description
99.1	Press Release dated January 12, 2020
104	Cover Page Interactive Data File

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 thereunto duly authorized.

NEUROCRINE BIOSCIENCES, INC.

Date: January 13, 2020

/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 2019 Net Product Sales Results and 2020 Program Milestones

- *INGREZZA® (valbenazine) Preliminary Fourth Quarter Net Product Sales of Approximately $238 Million with Approximately 42,100 TRx*

- *INGREZZA® (valbenazine) Preliminary Full-Year 2019 Net Product Sales of Approximately $753 Million with Approximately 132,700 TRx*

SAN DIEGO, Jan. 12, 2020 - Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today provided an update on its business performance, including preliminary net product sales results for 2019, and key commercial and clinical development milestones for 2020. Kevin Gorman, Chief Executive Officer of Neurocrine Biosciences, will discuss these updates as part of a webcast presentation at the 38th Annual J.P. Morgan Healthcare Conference in San Francisco on Monday, Jan. 13 at 11:30 a.m. Pacific Time (2:30 p.m. Eastern Time).

Preliminary Fourth Quarter and Full-Year 2019 INGREZZA® (valbenazine) Net Product Sales and Financial Results (Unaudited)

Based on preliminary unaudited financial information, the Company expects INGREZZA net product sales for the three months and full-year ended December 31, 2019 to be approximately $238 million and $753 million, respectively, compared to $130 million and $410 million for the same periods in 2018. Preliminary analysis of INGREZZA net product sales and TRx for the fourth quarter 2019 compared to third quarter 2019 suggests:

- Continued strength in new patient additions
- End of fourth quarter days-on-hand channel inventory increased relative to the third quarter due to timing of quarter-end purchases resulting in an approximate $11 million benefit to net product sales. Given the increase to year-end channel inventory, the Company anticipates this may lead to a reduction to channel inventory in the first quarter of 2020.
- INGREZZA net product sales per prescription of $5,650 for the fourth quarter of 2019

Preliminary unaudited cash and marketable securities balance as of December 31, 2019 is $970 million.

“Our results reflect our team’s dedication to educating healthcare providers and patients about tardive dyskinesia as seen in the growing number of patients receiving treatment with INGREZZA. We still have a lot of work to do as a majority of people suffering from tardive dyskinesia remain undiagnosed and untreated,” said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. “In 2020, we aim to have three FDA-approved medicines in four indications and will remain focused on helping more tardive dyskinesia patients with INGREZZA, preparing for the anticipated approval of opicapone in the U.S., and advancing our growing pipeline, including three pivotal clinical trial programs. We are well positioned as we evolve towards becoming a leading global neuroscience-focused biopharmaceutical company.”

Exhibit 99.1

2020 INGREZZA Net Product Sales Outlook

During the first quarter of 2020, the Company expects INGREZZA net product sales to be impacted as a result of payer-related seasonal dynamics, gross-to-net discount increases from payer and Medicare Part D rebates, and potential reduction in channel inventory. The Company does not intend to provide formal INGREZZA net product sales guidance for 2020 as the tardive dyskinesia market continues to evolve.

2020 Expected Milestones and Key Activities

INGREZZA (valbenazine) for Tardive Dyskinesia

- "Talk About TD" disease state awareness campaign
- Continued 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)
- Regulatory submissions for approval by Mitsubishi Tanabe in ASEAN territory

Valbenazine for Chorea in Huntington Disease

- Advance the current Phase III study recruitment and initiate open label portion of study during 1H 2020

Elagolix in Collaboration with AbbVie

- Prescription Drug User Fee Act (PDUFA) date in Q2 2020 of elagolix for uterine fibroids
- Continued launch of ORILISSA® (elagolix) to treat moderate to severe pain associated with endometriosis by AbbVie

Opicapone for Parkinson's Disease

- PDUFA date of April 26, 2020
- Preparation for commercial launch
- Presentations at key scientific annual meetings, including AAN, MDS

Crinecerfont (NBI-74788) for Congenital Adrenal Hyperplasia (CAH)

- Phase IIa data (adults) oral presentation in March at ENDO 2020
- Global registrational study initiation (adults) in mid-2020
- Advancement of pediatric plan including Phase IIa study

NBIb-1817 (VY-AADC) for Parkinson's Disease

- Present 3yr follow up data from study PD-1101 at appropriate medical conference
- Implement amended protocol for RESTORE-1 registration trial by mid-year based upon feedback from the U.S. Food and Drug Administration (FDA)
- Initiate RESTORE-II registration trial in 2H 2020

NBI-921352 (XEN901) for Epilepsy

- File Investigational New Drug (IND) application with the FDA in mid-2020 in order to start a Phase II trial in SCN8A developmental and epileptic encephalopathy patients in 2H 2020

ACT-709478 for Epilepsy

- Upon IND application acceptance by the FDA, expected in mid-2020, the Company will have 30 days to exercise the option to license ACT-709478
- A Phase II study in a rare pediatric epilepsy is planned in 2H 2020

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.

Parkinsonism

INGREZZA may cause Parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. Reduce the dose or discontinue INGREZZA treatment in patients who develop clinically significant parkinson-like signs or symptoms.

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 (Nasdaq: NBIX) is a neuroscience-focused, biopharmaceutical company with more than 25 years of experience discovering and developing life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia and endometriosis* and clinical development programs in multiple therapeutic areas including Parkinson's disease, chorea in Huntington disease, congenital adrenal hyperplasia, epilepsy, uterine fibroids* and polycystic ovary syndrome*. Headquartered in San Diego, Neurocrine Biosciences specializes in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. For more information, visit neurocrine.com, and follow the company on LinkedIn. (**in collaboration with AbbVie*)

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 unaudited financial information; the benefits to be derived from our 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; the opicapone NDA; our financial and operating performance, including our future expenses; our collaborative partnerships; 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 the financial statement closing process that cause adjustments to the estimates included in this press release; our future financial and operating performance; risks associated with the commercialization of INGREZZA and ORILISSA; risks that the opicapone NDA may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks related to the development of our product candidates; risks associated with our dependence on third parties for development and manufacturing activities related to INGREZZA and our product candidates, and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks associated with our dependence on AbbVie for the commercialization of ORILISSA and the continued development of elagolix; risks associated with our dependence on BIAL for development and manufacturing activities related to opicapone, and our ability to manage BIAL; risks that clinical development activities may not be completed on time or at all, or may be delayed for regulatory, manufacturing, 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 potential

benefits of the agreements with our collaboration partners may never be realized; risks that our products, 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 our periodic reports filed with the SEC, including without limitation our quarterly report on Form 10-Q for the quarter ended September 30, 2019. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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