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 8, 2021

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 8, 2021, Neurocrine Biosciences, Inc. (the "Company"), issued a press release announcing preliminary fourth quarter 2020 and full year 2020 net product sales results. The Company's financial statements for the fourth quarter 2020 and full year 2020 have not yet been completed and could result in changes to these preliminary net product sales results. The press release also contained certain 2021 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 8, 2021
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.

Dated: January 8, 2021

/s/ Darin M. Lippoldt

Darin M. Lippoldt

Chief Legal Officer

Exhibit 99.1

Neurocrine Biosciences Provides Preliminary Fourth Quarter and Full-Year 2020 Net Product Sales Results and 2021 Program Milestones

INGREZZA® (valbenazine) Preliminary Fourth Quarter Net Product Sales and Inventory Adjusted Net Product Sales of Approximately $240 Million and $258 Million, Respectively

INGREZZA® (valbenazine) Preliminary Full-Year 2020 Net Product Sales and TRx Both Grew 32% to Approximately $993 Million and 175,700 TRx Respectively Versus the Prior Year

Company Plans to Provide Clinical Data for Key Programs and Expects to Initiate Seven Additional Mid-to-Late Stage Clinical Studies in 2021 for Neurological, Endocrine and Psychiatric Disorders

SAN DIEGO, Jan. 8, 2021 - Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today provided an update on its business performance, including preliminary net product and inventory adjusted sales results of INGREZZA® (valbenazine) for 2020, and key commercial and clinical development milestones for 2021. Kevin Gorman, Chief Executive Officer of Neurocrine Biosciences, will discuss these updates as part of a webcast presentation at the 39th Annual J.P. Morgan Healthcare Conference to be held virtually on Monday, January 11 at 2:00 p.m. Eastern Time, followed by a Question and Answer session at approximately 2:20 p.m. Eastern Time.

Preliminary Fourth Quarter and Full-Year 2020 INGREZZA® (valbenazine) Net Product Sales and Inventory Adjusted Net Product Sales (Unaudited)

Based on preliminary unaudited financial information, the Company expects INGREZZA net product sales for the three months and full-year ended December 31, 2020 to be approximately $240 million and $993 million respectively. Preliminary analysis of INGREZZA net product sales suggests:

- INGREZZA inventory adjusted net product sales for the fourth quarter were approximately $258 million reflecting an $18 million channel inventory decrease in Q4
- New prescriptions and refills increased in the fourth quarter of 2020 vs. the third quarter of 2020
- Full-year 2020 total INGREZZA prescriptions grew 32% to approximately 175,700 versus 2019 total prescriptions of approximately 132,700

“I am very proud of our team’s resilience and adaptability to bring INGREZZA to patients living with tardive dyskinesia this past year and we remain encouraged by the continued strength in persistence and refill rates, which is a testament to the many benefits of INGREZZA. We also continue to focus on healthcare provider educational initiatives, patient outreach programs and investing in telemedicine capabilities to improve diagnosis and treatment rates for the estimated 80% of patients with tardive dyskinesia who have not yet been diagnosed,” said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. “Adding to our movement disorder portfolio, we launched our second commercial treatment, ONGENTYS, and continue to make great progress in our development programs with plans to initiate seven mid-to-late stage clinical studies in 2021 focused on neurological, endocrine and psychiatric disorders.”

2021 Expected Milestones and Key Activities

Program	Indication	2021 Milestones / Key Activities
Valbenazine	Chorea in Huntington Disease	Phase III Top-Line Data Expected in Q4 2021
	Neurological Indication	Initiate Phase III
	Psychiatric Indication	Initiate Phase II
Crinecerfont	Congenital Adrenal Hyperplasia (Adult)	Continue Phase III Enrollment
	Congenital Adrenal Hyperplasia (Pediatric)	Initiate Phase III
NBI-1065844	Negative Symptoms of Schizophrenia	Phase II Top-Line Data Expected in 1st Half of 2021
NBI-1065845	Treatment Resistant Depression	Initiate Phase II
NBI-1065846	Anhedonia in Depression	Initiate Phase II
NBI-827104	Rare Pediatric Epilepsy: Epileptic Encephalopathy with Continuous Spike and Wave During Sleep	Continue Phase II Enrollment
	Neurological Indication	Initiate Phase II
NBI-921352	Focal Onset Seizure in Adults	Initiate Phase II
	Rare Pediatric Epilepsy: SCN8A-DEE	Ongoing Dialogue with FDA
NBIb-1817	Gene Therapy for Parkinson's Disease	Determine Regulatory Path with FDA

About Tardive Dyskinesia (TD)

Tardive dyskinesia (TD) is a movement disorder that is characterized by uncontrollable, abnormal and repetitive movements of the face, torso and/or other body parts, which may be disruptive and negatively impact patients. The condition is caused by prolonged use of treatments that block dopamine receptors in the brain, such as antipsychotics commonly prescribed to treat mental illnesses such as schizophrenia, bipolar disorder and depression, and certain anti-nausea medications. In patients with TD, these treatments are thought to result in irregular dopamine signaling in a region of the brain that controls movement. The symptoms of TD can be severe and are often persistent and irreversible. TD is estimated to affect at least 500,000 people in the U.S.

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 Biosciences'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 Information

Approved Use

INGREZZA® (valbenazine) capsules is a prescription medicine used to treat adults with movements in the face, tongue, or other body parts that cannot be controlled (tardive dyskinesia).

It is not known if INGREZZA is safe and effective in children.

Important Safety Information

Do not take INGREZZA if you are allergic to valbenazine, or any of the ingredients in INGREZZA.

INGREZZA may cause serious side effects, including:

- **Sleepiness (somnolence).** Do not drive, operate heavy machinery, or do other dangerous activities until you know how INGREZZA affects you.
- **Heart rhythm problems (QT prolongation).** INGREZZA may cause a heart problem known as QT prolongation.
- **Symptoms of QT prolongation may include**: fast, slow, or irregular heartbeat, shortness of breath, dizziness or fainting.
- **Parkinson-like symptoms**. Symptoms include: shaking, body stiffness, trouble moving or walking, or keeping your balance.

Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you faint.

Before taking INGREZZA, tell your healthcare provider about all of your medical conditions including if you: have liver or heart problems, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

The most common side effect of INGREZZA is sleepiness (somnolence). Other side effects include changes in balance (balance problems, dizziness) or an increased risk of falls, headache, feelings of restlessness, dry mouth, constipation, and blurred vision.

These are not all of the possible side effects of INGREZZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see INGREZZA full **Product Information**.

About Neurocrine Biosciences

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company dedicated to discovering, developing and delivering 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, Parkinson's disease, endometriosis*, uterine fibroids* and clinical programs in multiple therapeutic areas. For nearly three decades, Neurocrine Biosciences has specialized 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; the value our products and/or our product candidates may bring to patients; the continued success of INGREZZA; our financial and operating performance, our collaborative partnerships; expectations regarding the impact of COVID-19 on our business, including patient and healthcare provider access to INGREZZA, our ability to continue our ongoing clinical trials and other development activities, and to otherwise advance our business objectives; 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 ONGENTYS; the impact of the COVID-19 pandemic on our business and the business operations of our customers; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; risk and uncertainties related to any COVID-19 quarantines, shelter-in-place, social distancing and other government orders that are currently in place or that may be put in place in the future, including the impact of such orders on our business operations and the business operations of the third parties on which we rely; 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 ORIAHNN, as well as the continued development of elagolix; risks associated with our dependence on BIAL for manufacturing activities for ONGENTYS, 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, COVID-19 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, 2020. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

This press release refers to preliminary unaudited net sales in certain non-GAAP financial measures. These non-GAAP financial measures should not be considered replacements for, and should be read together with, the comparable GAAP financial measures, which are included in this press release.

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