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): **December 20, 2024**

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.)

6027 Edgewood Bend Court	
San Diego, California	**92130**
(Address of Principal Executive Offices)	(Zip Code)

(858) 617-7600
(Registrant's telephone number, including area code)

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))

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

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 December 20, 2024, Neurocrine Biosciences, Inc. ("Neurocrine Biosciences" or the "Company") issued a press release announcing that CRENESSITY™ (crinecerfont) capsules and oral solution are now available in the United States. CRENESSITY was recently approved by the U.S. Food and Drug Administration as an adjunctive treatment to glucocorticoid replacement to control androgens in adult and pediatric patients four years of age and older with classic congenital adrenal hyperplasia. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The Company has established a wholesale acquisition cost for CRENESSITY in the United States of approximately $38,333 for a 30-day supply. For pediatric patients weighing less than 20 kilograms, the wholesale acquisition cost for a 30-day supply will be approximately $19,167. The Company expects 90% of patients will have a monthly copay of $12 or less.

Forward-Looking Statements

In addition to historical facts, this Current Report on Form 8-K contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements regarding the potential benefits to be derived from CRENESSITY for the treatment of classic congenital adrenal hyperplasia due to 21-hydroxylase deficiency; the ability of the Company to ensure patients have access to CRENESSITY; and the Company's expectations regarding coverage and reimbursement from third-party payors for CRENESSITY. Factors that could cause actual results to differ materially from those stated or implied in the forward-looking statements include, but are not limited to, the following: risks and uncertainties associated with Neurocrine Biosciences' business and finances in general, as well as risks and uncertainties associated with the commercialization of CRENESSITY; whether CRENESSITY receives adequate reimbursement from third-party payors; risks associated with the Company's dependence on third parties for development and manufacturing activities related to CRENESSITY, and the ability of the Company to manage these third parties; 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, 2024. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof other than required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Neurocrine Biosciences, Inc. on December 20, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: December 20, 2024

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

Exhibit 99.1

Neurocrine Biosciences Announces Commercial Availability of CRENESSITY™ (crinecerfont) for Children and Adults With Classic Congenital Adrenal Hyperplasia

- CRENESSITY, a First-in-Class Treatment for Classic Congenital Adrenal Hyperplasia (CAH), is now commercially available in the U.S.
- CAH-trained pharmacists are available 24/7 to support patients with prescriptions exclusively through PANTHERx Rare, a specialty pharmacy
- Neurocrine Access Support is available to provide free, comprehensive access and support information to patients, caregivers and healthcare providers

SAN DIEGO, Dec. 20, 2024 – Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced CRENESSITY™ (crinecerfont) is now commercially available in the United States. CRENESSITY was recently approved by the U.S. Food and Drug Administration as an adjunctive treatment to glucocorticoid replacement to control androgens in adult and pediatric patients four years of age and older with classic congenital adrenal hyperplasia (CAH).

CRENESSITY, a potent and selective oral corticotropin-releasing factor type 1 receptor (CRF1) antagonist, is a first-in-class therapy for classic CAH that directly reduces adrenocorticotropic hormone and downstream adrenal androgen production. It is the first and only classic CAH treatment that allows people to take lower doses of glucocorticoids while maintaining or improving their androgen levels.

“Individuals with CAH and their families have faced ongoing challenges with managing the condition with high-dose steroids alone for the past 70 years,” said Kyle W. Gano, Ph.D., Chief Executive Officer, Neurocrine Biosciences. “We’re proud to now provide CRENESSITY to the community, and we are committed to supporting patients in obtaining treatment with CRENESSITY through our comprehensive assistance program.”

CRENESSITY is exclusively available through PANTHERx Rare, a specialty pharmacy, to centralize and simplify CRENESSITY prescriptions. PANTHERx Rare has CAH-trained pharmacists available 24/7 to patients, caregivers and healthcare providers to answer questions and address concerns.

Neurocrine Biosciences is committed to supporting patients in obtaining treatment with CRENESSITY by offering Neurocrine Access Support, a free, comprehensive assistance program created for patients, caregivers and healthcare providers. It offers a range of options specifically designed to ensure patients with CAH have everything they need to begin and continue taking CRENESSITY. A dedicated Care Coordinator, backed by a team, is available to help patients and caregivers navigate the insurance process and identify appropriate financial assistance options. The company expects 90% of patients will have a monthly copay of $12 or less. For more information, visit www.nbiaccess.com/crenessity or call 1-855-CRNSITY (276-7489) Monday-Friday 8 am-8 pm ET.

The U.S. Food and Drug Administration approval of CRENESSITY was supported by the largest-ever clinical trial program of classic CAH, the CAHtalystTM Pediatric study, conducted in ages four to 17, and the CAHtalyst Adult study.

View the press release announcing the initial FDA approval of CRENESSITY here.

For more information about CRENESSITY, visit Crenessity.com.

About Congenital Adrenal Hyperplasia
Congenital adrenal hyperplasia (CAH) is a rare genetic condition that results in an enzyme deficiency that alters the production of adrenal steroid hormones, such as cortisol, aldosterone and adrenal androgens, which are essential for life. Approximately 95% of CAH cases are caused by variants of the CYP21A2 gene that leads to deficiency of the enzyme 21-hydroxylase (21-OH). Severe deficiency of this enzyme leads to an inability of the adrenal glands to produce enough cortisol and, in approximately 75% of cases, aldosterone. Because individuals with CAH are still able to produce androgens, the unused precursors that would normally be used to make cortisol instead result in the production of excess amounts of androgens. If left untreated, CAH can result in salt wasting, dehydration and even death.

Historically, exogenous glucocorticoids (GCs) have been used not only to correct the endogenous cortisol deficiency, but doses used are higher than cortisol replacement needed (supraphysiologic) to lower the levels of adrenocorticotropic hormone (ACTH) and adrenal androgens. However, GC treatment at high doses has been associated with serious and significant complications of steroid excess, including metabolic issues such as weight gain and diabetes, cardiovascular disease and osteoporosis. Additionally, long-term treatment with high-dose GCs may have psychological and cognitive impact, such as changes in mood and memory. Adrenal androgen excess has been associated with abnormal bone growth and development in pediatric patients, female health problems such as excess facial hair growth and menstrual irregularities, testicular rest tumors in males and fertility issues in both sexes.

About The CAHtalyst™ Studies
The Phase 3 CAHtalyst™ global registrational studies were designed to evaluate the safety, efficacy and tolerability of CRENESSITY in children and adults with classic congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency. The CAHtalyst studies were the largest-ever clinical trial program in classic CAH, including 285 pediatric and adult patients.

The CAHtalyst Pediatric study included 103 pediatric patients aged four to 17 years. The study tested two questions. The first question evaluated whether four weeks of CRENESSITY treatment could improve androgen control. The second question evaluated whether an additional 24 weeks of CRENESSITY treatment enabled customized glucocorticoid (GC) down-titration while androstenedione levels were maintained or improved. The CAHtalyst Adult study included 182 adult patients aged 18 to 58 years. Similarly, the first question of the study evaluated whether four weeks of CRENESSITY treatment could improve androgen control, and the second question evaluated whether an additional 20 weeks of CRENESSITY treatment enabled GC reduction to physiologic range while androstenedione levels were maintained or improved.

Data from the CAHtalyst Phase 3 studies supported approval of CRENESSITY by the U.S. Food and Drug Administration in December 2024. The open-label extension treatment portions of both studies are ongoing.

About CRENESSITY™ (crinecerfont)
CRENESSITY™ is a potent and selective, oral corticotropin-releasing factor type 1 receptor (CRF1) antagonist developed to reduce and control excess adrenocorticotropic hormone (ACTH) and adrenal androgens through a non-glucocorticoid (GC) mechanism for the treatment of classic congenital adrenal hyperplasia (CAH). Antagonism of CRF1 receptors in the pituitary has been shown to decrease ACTH levels, which in turn decreases the production of adrenal androgens and potentially the symptoms associated with CAH. The robust clinical study data demonstrate that lowering adrenal androgen levels with CRENESSITY enables lower, more physiologic dosing of GCs to replace missing cortisol.

CRENESSITY comes in capsules and an oral solution. The capsule formulation is available in 50 mg and 100 mg doses. The oral solution is available as a 50 mg/mL strength formulation. For adults 18 years and older, the recommended dosage is 100 mg twice daily taken orally with a meal. For pediatric patients four to 17 years of age weighing less than 55 kg (121 lbs), the recommended dosage is based on body weight and is administered twice daily, taken orally with a meal. For pediatric patients weighing more than 55 kg (121 lbs), the recommended dosage is 100 mg twice daily taken orally with a meal. Healthcare providers can work with patients to determine the appropriate formulation for use depending on patient needs. Patients receiving CRENESSITY should continue GC therapy for cortisol replacement.

Important Information

Approved Uses
CRENESSITY (crinecerfont) is a prescription medicine used together with glucocorticoids (steroids) to control androgen (testosterone-like hormone) levels in adults and children 4 years of age and older with classic congenital adrenal hyperplasia (CAH).

IMPORTANT SAFETY INFORMATION

Do not take CRENESSITY if you:

Are allergic to crinecerfont, or any of the ingredients in CRENESSITY.

CRENESSITY may cause serious side effects, including:

Allergic Reactions. Symptoms of an allergic reaction include tightness of the throat, trouble breathing or swallowing, swelling of the lips, tongue, or face, and rash. If you have an allergic reaction to CRENESSITY, get emergency medical help right away and stop taking CRENESSITY.

Risk of Sudden Adrenal Insufficiency or Adrenal Crisis With Too Little Glucocorticoid (Steroid) Medicine. Sudden adrenal insufficiency or adrenal crisis can happen in people with congenital adrenal hyperplasia who are not taking enough glucocorticoid (steroid) medicine. You should continue taking your glucocorticoid (steroid) medicine during treatment with CRENESSITY. Certain conditions such as infection, severe injury, or shock may increase your risk for sudden adrenal insufficiency or adrenal crisis. Tell your healthcare provider if you get a severe injury, infection, illness, or have planned surgery during treatment. Your healthcare provider may need to change your dose of glucocorticoid (steroid) medicine.

Before taking CRENESSITY, tell your healthcare provider about all of your medical conditions, including if you 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 effects of CRENESSITY in adults include tiredness, headache, dizziness, joint pain, back pain, decreased appetite, and muscle pain.

The most common side effects of CRENESSITY in children include headache, stomach pain, tiredness, nasal congestion, and nose bleeds.

These are not all the possible side effects of CRENESSITY. Call your healthcare provider for medical advice about side effects. 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.

Dosage Forms and Strengths: CRENESSITY is available in 50 mg and 100 mg capsules and as an oral solution of 50 mg/mL.

Please see full Prescribing Information.

About Neurocrine Biosciences, Inc.
Neurocrine Biosciences is a leading neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, chorea associated with Huntington's disease, classic congenital adrenal hyperplasia, endometriosis* and uterine fibroids,* as well as a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn, X (formerly Twitter) and Facebook. (**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 regarding the potential benefits to be derived from CRENESSITY for the treatment of classic congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency; the value and benefits CRENESSITY brings to patients with CAH; the ability of Neurocrine Biosciences to ensure patients have access to CRENESSITY; and whether the results from our clinical trials of CRENESSITY are indicative of real-world results. Factors that could cause actual results to differ materially from those stated or implied in the forward-looking statements include, but are not limited to, the following: risks and uncertainties associated with Neurocrine Biosciences' business and finances in general, as well as risks and uncertainties associated with the commercialization of CRENESSITY; whether CRENESSITY receives adequate reimbursement from third-party payors; the degree and pace of market uptake of CRENESSITY; risks and uncertainties relating to competitive products and technological changes that may limit demand for CRENESSITY; risks associated with the Company's dependence on third parties for development and manufacturing activities related to CRENESSITY, and the ability of the Company to manage these third parties; risks that additional regulatory submissions for CRENESSITY or other product candidates may not occur or be submitted in a timely manner; risks that the FDA or other regulatory authorities may make adverse decisions regarding CRENESSITY; risks that post-approval CRENESSITY commitments or requirements may be delayed; risks that CRENESSITY 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; risks and uncertainties relating to competitive products and technological changes that may limit demand for CRENESSITY; 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, 2024. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof other than required by law.

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