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): November 2, 2021

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**001-12400**	**94-3136539**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1801 Augustine Cut-Off Wilmington, DE	**19803**
(Address of principal executive offices)	(Zip Code)

(302) 498-6700
(Registrant's telephone number, including area code)

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 obligations of the registrant under any of the following provisions (see General Instruction 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))

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

Title of each class	**Trading Symbol**	**Name of exchange on which registered**
Common Stock, $.001 par value per share	INCY	The Nasdaq Stock Market LLC

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 7.01 Regulation FD Disclosure.

On November 2, 2021, Incyte Corporation (the "Company") issued a corporate statement providing additional information with respect to certain statements made during the Company's third quarter of 2021 earnings call on November 2, 2021.

Item 9.01 Financial Statements and Exhibits.

(d) **Exhibits.**

Exhibits	Description
99.1	Corporate Statement issued by Incyte Corporation on November 2, 2021.

SIGNATURE

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.

Date: November 2, 2021

INCYTE CORPORATION

By: **/s/ Maria E. Pasquale**
Maria E. Pasquale
Executive Vice President and General Counsel

Exhibit 99.1

Corporate Statement Regarding Opzelura™ (ruxolitinib) Cream

WILMINGTON, Del. – November 2, 2021 – This morning, as part of our Q3 2021 earnings call, we addressed a question related to samples and commercial supply of Opzelura™ (ruxolitinib) cream.

As of today, we have received three product complaints related to texture. As is standard with a product report of this kind, we are following all regulations and protocols including informing the U.S. Food and Drug Administration, investigating the complaints and conducting a thorough root cause analysis across all batches to ensure continued product quality and supply.

Early analytical testing of both the 5 gram and 60 gram batches of Opzelura in question do not show any issues that would impact the safety or efficacy of the product. The texture issue is related to a very small quantity of active product ingredient (API) not being completely dissolved, which has, on occasion, produced a slight gritty texture.

In response to the product complaints, distribution of the affected batches of product have been suspended.

At this time, we have no commercial supply issues. Sixty gram tubes of Opzelura, which have passed release and 90-day quality control testing, remain available for distribution and additional batches of product continue to be manufactured.

About Opzelura™ (ruxolitinib) Cream
Opzelura, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, is the first and only topical JAK inhibitor approved for use in the United States for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants, such as azathioprine or cyclosporine, is not recommended.

Additionally, ruxolitinib cream is in Phase 3 development for the treatment of adolescents and adults with vitiligo in the TRuE-V clinical program. Results from this Phase 3 program were recently announced.

Incyte has worldwide rights for the development and commercialization of ruxolitinib cream, marketed in the United States as Opzelura.

Opzelura is a trademark of Incyte.

IMPORTANT SAFETY INFORMATION

OPZELURA cream is for use on the skin only. Do not use OPZELURA cream in your eyes, mouth or vagina.

OPZELURA may cause serious side effects, including:

Serious Infections: OPZELURA cream contains ruxolitinib. Ruxolitinib belongs to a class of medicines called Janus kinase (JAK) inhibitors. JAK inhibitors are medicines that affect your immune system. JAK inhibitors can lower the ability of your immune system to fight infections. Some people have had serious infections while taking JAK inhibitors by mouth, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have been hospitalized or died from these infections. Some people have had serious infections of their lungs while taking OPZELURA. Your healthcare provider should watch you closely for signs and symptoms of TB during treatment with OPZELURA.

OPZELURA should not be used in people with an active, serious infection, including localized infections. You should not start using OPZELURA if you have any kind of infection unless your healthcare provider tells you it is okay. You may be at a higher risk of developing shingles (herpes zoster) while using OPZELURA.

Increased risk of death from all causes, including sudden cardiac death, has happened in people taking JAK inhibitors by mouth.

Cancer and immune system problems: OPZELURA may increase your risk of certain cancers by changing the way your immune system works. Some people have had lymphoma and other cancers while taking JAK inhibitors by mouth, especially if they are a current or past smoker. Some people have had skin cancers while taking OPZELURA. Your healthcare provider will regularly check your skin during your treatment with OPZELURA.

There is an increased risk of major cardiovascular events such as heart attack, stroke or cardiac death in people with cardiovascular risk factors and who are current or past smokers while using JAK inhibitors to treat inflammatory conditions.

Blood clots: Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) can happen in some people taking OPZELURA. This may be life-threatening.

Low blood cell counts: OPZELURA may cause low platelet counts (thrombocytopenia), low red blood cell counts (anemia), and low white blood cell counts (neutropenia). If needed, your healthcare provider will do a blood test to check your blood cell counts during your treatment with OPZELURA and may stop your treatment if signs or symptoms of low blood cell counts happen.

Cholesterol increases: Cholesterol increase has happened in people when ruxolitinib is taken by mouth. Tell your healthcare provider if you have high cholesterol or triglycerides.

Before starting OPZELURA, tell your healthcare provider if you:

- have an infection, are being treated for one, or have an infection that keeps coming back
- have diabetes, chronic lung disease, HIV, or a weak immune system
- have TB or have been in close contact with someone with TB
- have had shingles (herpes zoster) or hepatitis B or C
- live, have lived in, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections. These infections may happen or become more severe if you use OPZELURA. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
- think you have an infection or have symptoms of an infection such as:
  - fever, sweating, or chills
  - muscle aches
  - cough or shortness of breath
  - blood in your phlegm
  - weight loss
  - warm, red, or painful skin or sores on your body
  - diarrhea or stomach pain
  - burning when you urinate or urinating more often than usual
  - feeling very tired
- have ever had any type of cancer, or are a current or past smoker.
- have had blood clots in the veins of your legs or lungs in the past.
- have high cholesterol or triglycerides
- have or have had low white or red blood cell counts
- are pregnant or plan to become pregnant. It is not known if OPZELURA will harm your unborn baby. There is a pregnancy exposure registry for individuals who use OPZELURA during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. If you become exposed to OPZELURA during pregnancy, you and your healthcare provider should report exposure to Incyte Corporation at 1-855-463-3463.
- are breastfeeding or plan to breastfeed. It is not known if OPZELURA passes into your breast milk. Do not breastfeed during treatment with OPZELURA and for about 4 weeks after the last dose.

After starting OPZELURA:

- Call your healthcare provider right away if you have any symptoms of an infection. OPZELURA can make you more likely to get infections or make worse any infections that you have.
- Get emergency help right away if you have any symptoms of a heart attack or stroke while using OPZELURA, including:
  - discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
  - severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
  - pain or discomfort in your arms, back, neck, jaw, or stomach
  - shortness of breath with or without chest discomfort
  - breaking out in a cold sweat
  - nausea or vomiting
  - feeling lightheaded
  - weakness in one part or on one side of your body
  - slurred speech
- Tell your healthcare provider right away if you have any signs and symptoms of blood clots during treatment with OPZELURA, including: swelling, pain or tenderness in one or both legs, sudden, unexplained chest or upper back pain, or shortness of breath or difficulty breathing.
- Tell your healthcare provider right away if you develop or have worsening of any symptoms of low blood cell counts, such as: unusual bleeding, bruising, tiredness, shortness of breath or fever.

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 OPZELURA include: pain or swelling in your nose or throat (nasopharyngitis), diarrhea, bronchitis, ear infection, increase in a type of white blood cell counts (eosinophil), hives, inflamed hair pores (folliculitis), swelling of the tonsils (tonsilitis), and runny nose (rhinorrhea).

These are not all of the possible side effects of OPZELURA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Incyte Corporation at 1-855-463-3463.

About Incyte Dermatology

Incyte’s science-first approach and expertise in immunology has formed the foundation of the company. In Dermatology, the Company’s research and development efforts are focused on leveraging our knowledge of the JAK-STAT pathway to identify and develop topical and oral therapies with the potential to modulate immune pathways driving uncontrolled inflammation and help restore normal immune function.

Currently, Incyte is exploring the potential of JAK inhibition for a number of immune-mediated dermatologic conditions with a high unmet medical need, including vitiligo and hidradenitis suppurativa. To learn more, visit the Dermatology section of Incyte.com.

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

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