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): February 27, 2026

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 8.01 Other Events.

On February 27, 2026, the U.S. Food and Drug Administration ("FDA") issued a Complete Response Letter ("CRL") for the supplemental Biologics License Application ("sBLA") for Zynyz® (retifanlimab-dlwr) injection (375mg) for an additional indication for the treatment of adult patients with metastatic non-small cell lung cancer ("NSCLC") in combination with platinum-based chemotherapy. The sBLA was supported by positive efficacy and safety data from the Phase 3 POD1UM-304 trial announced in December 2024.

The CRL cited inspection findings (not specific to Zynyz) at Catalent Indiana, LLC ("Catalent Indiana"), part of Novo Nordisk, the third-party fill-finish facility referenced in the sBLA. The CRL cited the regulatory compliance of Catalent Indiana as the sole approvability issue, and did not cite other approvability concerns, including Zynyz's efficacy and safety data in NSCLC or the third-party drug substance manufacturer.

Incyte Corporation is working closely with the FDA and Catalent Indiana to address the CRL and support a potential sBLA resubmission of Zynyz in NSCLC.

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: March 6, 2026

INCYTE CORPORATION

By: /s/ Richard Hoffman

Richard Hoffman

Executive Vice President and General Counsel