INCYTE CORP
Form 8-K
April 17, 2017

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): **April 14, 2017**

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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 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 o

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. o

Item 8.01 **Other Events.**

On April 14, 2017, Eli Lilly and Company and Incyte Corporation announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter for the New Drug Application of the investigational medicine baricitinib, a once-daily oral medication for the treatment of moderate-to-severe rheumatoid arthritis.

The letter indicates that the FDA is unable to approve the application in its current form. Specifically, the FDA indicated that additional clinical data are needed to determine the most appropriate doses. The FDA also stated that additional data are necessary to further characterize safety concerns across treatment arms. The companies disagree with the FDA s conclusions. The timing of a resubmission will be based on further discussions with the FDA.

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.

Dated: April 17, 2017

INCYTE CORPORATION

By: /s/ Eric H. Siegel
Eric H. Siegel
Executive Vice President and General Counsel