Clovis Oncology, Inc.
Form 8-K
September 08, 2016

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): September 8, 2016

CLOVIS ONCOLOGY, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**001-35347**	**90-0475355**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

5500 Flatiron Parkway, Suite 100

Boulder, Colorado	**80301**
(Address of principal executive offices)	**(Zip code)**

(303) 625-5000

(Registrant s telephone number including area code)

N/A

(Former name and 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 obligation 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))

Item 8.01 Other Events.

The Food and Drug Administration (FDA) has notified Clovis Oncology, Inc. (the Company) that FDA is not currently planning to hold an advisory committee meeting to discuss the Company s New Drug Application for rucaparib. As previously announced by the Company, FDA has accepted the Company s NDA for accelerated approval of rucaparib and granted priority review status to the application with a Prescription Drug User Fee Act (PDUFA) date of February 23, 2017.

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.

CLOVIS ONCOLOGY, INC.

By: /s/ Paul E. Gross
Name: Paul E. Gross
Title: Senior Vice President & General Counsel

Dated: September 8, 2016