Clovis Oncology, Inc.
Form 8-K
April 12, 2019

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 12, 2019

Clovis Oncology, Inc.

(Exact name of registrant as specified in its charter)

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

5500 Flatiron Parkway, Suite 100

Boulder, Colorado	**80301**
(Address of principal	**(Zip Code)**

executive offices)

Registrant s telephone number, including area code: (303) 625-5000

Not Applicable

(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 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))
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.

Clovis Oncology, Inc. (Clovis) is discontinuing its sponsored Phase 2 open-label monotherapy clinical trial evaluating rucaparib in recurrent, metastatic bladder cancer (CO-338-085 (ATLAS)). The decision is based on recommendations by an independent data monitoring committee (DMC) following its review of preliminary efficacy data for 62 patients enrolled and treated in the study, which demonstrated that the objective response rate in the intent-to-treat population does not meet the protocol-defined continuance criteria, and suggests that treatment with monotherapy rucaparib may not provide a meaningful clinical benefit to patients. Therefore, the DMC recommended to stop enrollment to the study, and Clovis has decided to terminate the ATLAS trial early. The recommendation of the DMC was not based on the safety profile of rucaparib in this study population.

Clovis is continuing to evaluate the potential for rucaparib in combination with other agents for the treatment of advanced bladder cancer. Clovis also plans to enroll patients with advanced bladder cancer and selected genetic mutations in a planned pan-tumor trial of rucaparib expected to begin in the second half of 2019.

Forward Looking Statements

To the extent that statements contained in this report are not descriptions of historical facts regarding Clovis Oncology, they are forward-looking statements reflecting the current beliefs and expectations of management. Words such as believes, anticipates, plans, expects, indicates, will, intends, potential, suggests, assuming, designed, and similar expressions are intended to identify forward-looking statements. Examples of forward-looking statements contained in this report include, among others, statements regarding our plans to continue to evaluate the potential for rucaparib in combination with other agents for the treatment of advanced bladder cancer and our plans to enroll patients with advanced bladder cancer and selected genetic mutations in a planned future trial of rucaparib. Such forward-looking statements involve substantial risks and uncertainties that could cause our future results, performance or achievements to differ significantly from that expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, possible changes to our plans or priorities as we assess data, whether future study results will be consistent with study findings to date and whether future study results will support continued development or regulatory approval, and the initiation, enrollment, timing and results of our planned clinical trials. Clovis Oncology does not undertake to update or revise any forward-looking statements. A further description of risks and uncertainties can be found in Clovis Oncology s filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its reports on Form 10-Q and Form 8-K.

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.

CLOVIS ONCOLOGY, INC.

April 12, 2019

By: /s/ Paul E. Gross
Name: Paul E. Gross
Title: Executive Vice President, General Counsel and Chief Compliance Officer