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 14, 2022

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 executive offices) **(Zip Code)**

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))

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock par Value $0.001 per Share	**CLVS**	**The NASDAQ Global Select Market**

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 November 14, 2022, at the request of the FDA, Clovis Oncology, Inc. (the "Company") met by teleconference with the FDA to discuss the overall survival (OS) data from the Company's ARIEL3 clinical trial. The ARIEL3 dataset formed the basis for the approval of Rubraca in the US in April 2018 and in Europe in January 2019 respectively, as second-line maintenance treatment in adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. The Company submitted final OS data, including in exploratory subgroups, from the ARIEL3 study to the FDA in September 2022. The FDA requested that the Company voluntarily revise the label to limit the indication of Rubraca in this second-line maintenance treatment to tBRCA patients only. The FDA further indicated to the Company that if an agreement could not be reached on the revised indication, the FDA would convene an ODAC meeting to review this matter. The Company is currently evaluating FDA's request.

To the extent that statements contained in this current report are not descriptions of historical facts regarding Clovis Oncology, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Examples of forward-looking statements contained in this press release include, among others, statements of our expectations concerning future regulatory activities, expectations for submission of regulatory filings, our plans to submit additional data to, or meet with, the FDA with respect to the status of Rubraca's label. Such forward-looking statements involve substantial risks and uncertainties that could cause Clovis Oncology's actual results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in drug discovery and clinical development, including the actions by the FDA, the EMA or other regulatory authorities regarding data required to support drug applications and labeling. Clovis Oncology undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see Clovis Oncology's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and its other reports filed with the Securities and Exchange Commission.

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.

November 16, 2022

By: /s/ Paul Gross
Name: Paul Gross
Title: Executive Vice President and General Counsel