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): June 16, 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** **(Address of principal executive offices)**	**80301** **(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.

FAP-2286

On June 14, 2022, Clovis Oncology, Inc. (the "Company") announced initial Phase 1 data from the Company-sponsored Phase 1/2 LuMIERE clinical study (NCT04939610) investigating the safety, pharmacokinetics, dosimetry, and preliminary antitumor activity of its targeted radiotherapy candidate, FAP-2286 labelled with lutetium-177 (177Lu-FAP-2286). Overall, in nine patients treated in the first two dose cohorts, 177Lu-FAP-2286 demonstrated a manageable safety profile and encouraging evidence of activity, including a confirmed RECIST partial response in one patient.

In addition, on June 14, 2022, the Company announced that updated data from an investigator-initiated Phase 1 study of FAP-2286 labelled with gallium-68 (^{68}Ga-FAP-2286) as a novel imaging agent to identify metastatic cancer in patients with solid tumors were presented (NCT04621435) in an oral presentation at the Society of Nuclear Medicine & Molecular Imaging (SNMMI) Annual Meeting 2022 in Vancouver, British Columbia.

FAP-2286 targets fibroblast activation protein (FAP), a promising theranostic target with expression across many tumor types. FAP-2286 is the first peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting FAP to enter clinical development and is the lead candidate in the Company's targeted radionuclide therapy (TRT) development program. The Phase 1 portion of the LuMIERE study is evaluating the safety of the investigational therapeutic agent 177Lu-FAP-2286 to identify the recommended Phase 2 dose and schedule. The safety and tumor uptake of the imaging agent 68Ga-FAP-2286 is also being evaluated, with plans for Phase 2 expansion cohorts in multiple tumor types to initiate in the fourth quarter of 2022.

Initial results from the Phase 1 portion of the ongoing Phase 1/2 LuMIERE study found treatment-emergent adverse events (TEAEs) to be generally mild to moderate among the nine patients in the safety population receiving 3.7 or 5.55 GBq/dose of the investigational therapeutic agent 177Lu-FAP-2286. Three patients (33.3%) had a Grade ≥3 TEAE of back pain (11.1%), abdominal distension (11.1%), increased bilirubin (11.1%) and hyponatremia (11.1%); none were judged as related to 177Lu-FAP-2286. There was one serious adverse event (SAE) of back pain not related to 177Lu-FAP-2286. No dose-limiting toxicities were observed in the 3.7 or 5.55 GBq cohorts (n=3 evaluable in each cohort).

At the two dose levels evaluated to date, organ dosimetry revealed target organ exposure within the expected range to support administration of multiple doses. There was tumor uptake across a range of tumor types with prolonged tumor retention of 177Lu-FAP-2286 after dosing.

A confirmed RECIST partial response was reported in one heavily pre-treated patient in the 3.7 GBq dose cohort with pseudomyxoma peritonei of appendiceal origin who completed six administrations of 177Lu-FAP-2286. A decrease in the level of the serum tumor marker carcinoembryonic antigen (CEA) was also observed in the patient over the course of 177Lu-FAP-2286 administration.

Recruitment for the third dose cohort (7.4 GBq) is ongoing.

The Company expects to present additional clinical data from the LuMIERE study at another nuclear medical meeting and initiating Phase 2 expansion cohorts in multiple tumor types in the fourth quarter of 2022.

Rubraca (rucaparib)

The Company submitted to the FDA and EMA final overall survival (OS) data in primary efficacy populations from our ARIEL3 trial, the double-blind, multicenter clinical trial in which 564 patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who were in response to platinum-based chemotherapy were randomized to receive Rubraca or placebo. In the tBRCA population, the hazard ratio (HR) was 0.832 with a nominal p-value of 0.3162; in the HRD population, the HR was 1.005 with a nominal p-value of 0.9693 and in the Intent-to-Treat (ITT) population, the HR was 0.995 with a nominal p-value of 0.9621. The Company has submitted an abstract to present the full OS data from the ARIEL3 trial, including for the exploratory subgroups, at the Annual Global Meeting of the International Gynecological Cancer Society (IGCS) to be held in New York City from September 29 through October 1, 2022.

In addition, based on further discussions with the FDA following submission of ARIEL4 OS data previously disclosed, the Company elected to voluntarily withdraw the approval for Rubraca in the U.S. as treatment of BRCA-mutated ovarian cancer after two or more chemotherapies. This withdrawal became effective as of June 10, 2022 and does not affect other indications for Rubraca. The Company has voluntarily requested withdrawal of the treatment indication in Europe. As the Company has previously stated, the treatment indication currently represents a very small portion of the Company's total sales in both the U.S. and Europe, and with respect to Europe, this indication is currently only reimbursed in Germany and the Netherlands, though this withdrawal may have an impact on the Company's sales outside the treatment indication.

Based on the results of the monotherapy portion of the ATHENA Phase 3 trial (ATHENA-MONO), the Company is currently preparing an sNDA for submission to the FDA and, subject to EMA agreement, a Type II variation for submission to the EMA for a first-line maintenance treatment indication for women with advanced ovarian cancer who have responded to first-line platinum-based chemotherapy.

The FDA has accepted a request for a Type A meeting with the Company to discuss plans for this sNDA filing. Despite the fact that the ATHENA-MONO trial met its primary endpoint, and overall survival (OS) is a secondary endpoint, the FDA advised the Company in early May 2022 that it should not submit the first-line maintenance sNDA until OS data from the ATHENA-MONO trial are as much as 50% mature, and if the Company submits the sNDA prior to that, it should expect the FDA to require a discussion at an ODAC meeting in connection with its review of such sNDA submission. Currently, the OS data are approximately 25% mature and the Company's initial estimates suggest that 50% maturity would be reached in approximately 2 years.

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 intentions and expectations for our development and discovery programs, including the timing and pace of pre-clinical development, plans for clinical development, plans for additional applications of the FAP-2286 peptide, including potential indications, tumor types and combination trials, and regulatory plans with respect to FAP-2286, our expectations concerning future regulatory activities, expectations for submission of regulatory filings, our plans to present final or interim data on ongoing clinical trials, our plans to submit additional data to, or meet with, the FDA with respect to the status of or plans for ongoing or planned trials and regulatory submissions. 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 pre-clinical and clinical development, including the outcome of pre-clinical studies and clinical trials, whether initial results, findings or research will support future studies or development, whether future study results will be consistent with previous study findings or other results, including pre-clinical studies, results in named-patient or similar programs or clinical trials, whether additional studies not originally contemplated are determined to be necessary, the timing of initiation, enrollment and completion of planned studies and actions by the FDA, the EMA or other regulatory authorities regarding data required to support drug applications and whether to approve drug applications. 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.

June 16, 2022

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