Clovis Oncology, Inc. Form 8-K February 01, 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): January 30, 2017

### **CLOVIS ONCOLOGY, INC.**

(Exact name of registrant as specified in its charter)

Delaware 001-35347 90-0475355

(State or other jurisdiction of (Commission File Number) (I.R.S. Employer

incorporation or organization) 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 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:

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 1.01 Entry into a Material Definitive Agreement.

On January 30, 2017, Clovis Oncology, Inc. ("Clovis") and Strata Oncology, Inc. ("Strata") entered into a Strata Trial Collaboration Agreement (the "Agreement"), in order to identify potentially eligible patients for Clovis' ongoing TRITON (Trial of Rucaparib in Prostate Indications) clinical trial program, which includes Phase 2 and Phase 3 clinical trials of rucaparib in metastatic castration-resistant prostate cancer ("mCRPC"), via the Strata Trial (the "Strata Trial"), a nationwide observational study sponsored by Strata under which no-cost sequencing is provided to advanced cancer patients at Strata Trial sites.

The Agreement provides that Strata will provide no-cost tumor sequencing to patients at clinical sites that have agreed to participate in the Strata Trial, and match BRCA1, BRCA2 and ATM-mutated advanced prostate cancer patients to Clovis' TRITON2 and TRITON3 clinical trials for rucaparib. Strata has agreed not to provide similar matching services on behalf of any other Strata collaborator for any other mCRPC clinical trial with respect to patients having the same BRCA1, BRCA2 and ATM genetic mutations. Clovis is obligated to make an initial, one-time fee to Strata upon execution of the Agreement and, following matching of eligible patients to Clovis pursuant to the Agreement, if any such matched patients are enrolled in TRITON2 or TRITON3, Clovis shall be obligated to pay a per-patient fee, a portion of which is due upon enrollment and the remainder upon the first approval by the Food and Drug Administration of rucaparib for use in mCRPC. Upon such approval, if any, Clovis is also obligated to make a milestone payment to Strata that is calculated based on the percent of patients matched by Strata as a portion of the total enrolled patients in the dataset supporting such approval, with a minimum percentage specified to qualify for such milestone payment. While the final amount of aggregate per-patient fees and any milestone payment are unknown and dependent on variables such as total number of patients matched by Strata and enrolled in the TRITON trials and included in the dataset supporting approval, if any, we estimate the aggregate cost of the Agreement to range from less than \$1 million to up to several tens of millions of dollars.

Either party may terminate the Agreement following the first anniversary upon 90 days' prior written notice as specified in the Agreement. In addition, either party may terminate the Agreement due to a material breach of the Agreement by the other party, subject to prior written notice and a cure period, or in the event it is determined that the Agreement contravenes any law or regulation.

Strata may terminate the Agreement upon advance written notice in the event Clovis completes enrollment in all of the clinical trials covered by the Agreement, and may terminate the Agreement with respect to a particular clinical trial in the event Clovis ceases enrollment in, or stops, such clinical trial. Clovis may terminate the Agreement if Strata closes its trial collaboration with clinical study sites and clinical study sponsors.

Keith Flaherty, a member of the Board of Directors of Clovis, is also a founder, member of the board of directors and a stockholder of Strata. Accordingly, the Agreement constitutes a related party transaction under Item 404(a) of Regulation S-K and was reviewed and approved by the Audit Committee of Clovis' Board of Directors.

The foregoing is only a summary of certain provisions of the Agreement and is qualified in its entirety by the terms of the Agreement, a copy of which will be filed as an exhibit to Clovis' quarterly report on Form 10-Q for the quarter ending March 31, 2017.

The information in this report relating to the Company's estimates of its financial obligations under the Agreement 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. These statements involve substantial risks and uncertainties including, among others, risks and uncertainties associated with the enrollment in the TRITON trials, Strata's matching of patients to those trials and the dataset and approval, if any, of any indication covered by the Agreement. The Company undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties relating to the business of the Company in general, see the

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Company's filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.

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# **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.

Dated: February 1, 2017 By: /s/ Daniel Muehl

Name: Daniel Muehl

Title: Senior Vice President of Finance