Clovis Oncology, Inc.
Form 8-K
October 04, 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): October 3, 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 1.01 Entry into a Material Definitive Agreement.

On October 3, 2016, Clovis Oncology, Inc. (Clovis) and Lonza Ltd (Lonza) entered into a Manufacturing Services Agreement (the Agreement) for the long term manufacture and supply of the active pharmaceutical ingredient (API) for rucaparib. The terms and conditions of the Agreement are contingent upon the approval by the U.S. Food and Drug Administration of the initial New Drug Application for rucaparib, unless triggered earlier by Clovis. Clovis and Lonza are parties to a Development and Manufacturing Agreement, dated February 8, 2013, as amended, under which Lonza has supplied rucaparib API for clinical development.

The Agreement provides that Lonza will be a non-exclusive manufacturer of the rucaparib API during the term of the Agreement, which expires on December 31, 2025, unless extended by mutual written consent of the parties. Under the Agreement, Lonza will construct, in an existing Lonza facility, a production train that will be exclusively dedicated to the manufacture of the rucaparib API. The dedicated production train will provide manufacturing capacity to meet Clovis currently anticipated needs for commercial supply of rucaparib API.

Clovis is obligated to make scheduled capital program fee payments towards capital equipment and other costs associated with the construction of the dedicated production train and, once the facility is operational, Clovis is obligated to pay a fixed facility fee each quarter for the duration of the Agreement.

Pursuant to the terms of the Agreement, Lonza will manufacture and store an advanced intermediate to be used in the subsequent production of the rucaparib API. Clovis will pay fixed fees on a per kilogram basis for quantities of the advanced intermediate and the rucaparib API ordered by Clovis under the Agreement, subject to certain adjustments. Until the dedicated facility is completed and operationally qualified, Lonza will manufacture the rucaparib API in existing Lonza facilities at pricing established in the Agreement.

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. Clovis may terminate the Agreement, subject to 90 days prior written notice, in the event rucaparib is withdrawn from the market for certain reasons. In the event of such a termination by Clovis, or termination by Lonza due to material breach by Clovis, Clovis is obligated to compensate Lonza for any services rendered, or for which costs have been incurred by Lonza in anticipation of services to be provided to Clovis, and to pay to Lonza the remaining amount of any capital program fees and quarterly fixed facility fees for the remainder of the term of the Agreement. In the event the Agreement is terminated by Clovis due to material breach by Lonza, Lonza is obligated to repay all or a portion of the capital program fees previously paid by Clovis.

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 annual report on Form 10-K for the year ending December 31, 2016. Clovis intends to submit a Confidential Treatment Request to the SEC pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, requesting confidential treatment of certain portions of the Agreement.

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/ Daniel W. Muehl
Name: Daniel W. Muehl
Title: Senior Vice President of Finance

Dated: October 4, 2016