Clovis Oncology, Inc. Form 8-K May 02, 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): May 1, 2019

Clovis Oncology, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction

001-35347 (Commission

90-0475355 (I.R.S. Employer

of incorporation)

File Number)

Identification No.)

5500 Flatiron Parkway, Suite 100

80301

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Boulder, Colorado (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

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

Item 1.01. Entry into a Material Definitive Agreement

On May 1, 2019, Clovis Oncology, Inc., a Delaware corporation (the <u>Company</u>), and certain subsidiaries of the Company, as Guarantors, entered into a Financing Agreement (the _Financing Agreement) with certain affiliates of TPG Sixth Street Partners, LLC as lenders (collectively, the <u>Lenders</u>) and as the administrative agent. Under the terms of the Financing Agreement, the Company is expected to borrow from the Lenders amounts required to reimburse its actual expenses incurred during each fiscal quarter (limited to agreed budgeted amounts), as such expenses are incurred, related to the Company s ATHENA Trial, in an aggregate amount of up to \$175 million (the amount actually borrowed, the Borrowed Amount). The Company has agreed to repay such Borrowed Amount together with a return to the Lenders, as described below, from revenues generated from sales of Rubraca. The Company expects to incur the borrowings under the Finance Agreement on a quarterly basis, beginning with an initial draw of \$8.6 million upon the execution of the Financing Agreement with respect to such expenses incurred during the quarter ended March 31, 2019, and ending generally on the earliest to occur of (i) the termination of the ATHENA Trial, (ii) the date of completion of all activities under the ATHENA Trial Clinical Study Protocol (iii) the date on which the Company pays the Discharge Amount (as defined below), (iv) the date of the occurrence of a change of control of the Company (or a sale of all or substantially all of the assets of the Company related to Rubraca) or a receipt of notice by the Company of certain breaches by the Company of its obligations under its material in-license agreements related to Rubraca and (v) September 30, 2022 (the <u>Borrowing Period</u>).

Under the Financing Agreement, the Company is obligated to pay to the Lenders, on a quarterly basis, beginning on the earliest to occur of (i) the termination of the ATHENA Trial, (ii) the approval by the FDA of an update to the label portion of the Rubraca new drug application (NDA) to include in such label the treatment of an indication resulting from the ATHENA Trial, (iii) the date on which the Company determines that the results of the ATHENA Trial are insufficient to achieve such an expansion of the Rubraca label to cover an indication based on the ATHENA Trial and (iv) September 30, 2022 (the Repayment Start Date):

9.75% (which rate may be increased incrementally up to approximately 10.25% in the event the Borrowed Amount exceeds \$166.5 million) of the direct Rubraca net sales recorded by the Company and its subsidiaries worldwide and its future out-licensees in the United States, if any, during such quarter;

19.5% of any royalty payments received by the Company and its subsidiaries during such quarter based on the sales of Rubraca by its future out-licensees outside the United States, if any; and

19.5% of any other amounts received by the Company and its subsidiaries in connection with any other commercialization arrangement for Rubraca, including any upfront and milestone payments and proceeds of infringement claims (which payments are not subject to the caps described below).

The amounts required to be paid by the Company to the Lenders in any given calendar quarter will be capped at \$8.5 million, unless the label portion of the Rubraca NDA is expanded by the

FDA to include in such label the treatment of an indication resulting from the ATHENA Trial, in which case the amounts required to be paid by the Company to the Lenders in any given calendar quarter will be capped at \$13.5 million. In the event the Borrowed Amount exceeds \$166.5 million, such quarterly limits will be incrementally increased to a maximum of approximately \$8.94 million and \$14.19 million, respectively.

The maximum amount required to be repaid to the Lenders in respect of the Borrowed Amounts is two times the aggregate Borrowed Amount under the Financing Agreement (which may be \$350 million in the event the Company borrows the full \$175 million under the Financing Agreement). In the event the Company has not made payments to the Lenders on or before December 30, 2025 equal to at least the Borrowed Amount, the Company is required to make a lump sum payment to the Lenders in an amount equal to such Borrowed Amount less the aggregate of all prior quarterly payments described above. All other payments are contingent on the performance of Rubraca.

The obligations of the Company under the Financing Agreement will be secured under a Pledge and Security agreement (<u>Security Agreement</u>) by a first priority security interest in all assets of the Company related to Rubraca, including intellectual property rights and a pledge of the equity of the Company s wholly owned subsidiaries, Clovis Oncology UK Limited and Clovis Oncology Ireland Limited. In addition, the obligations of the Company under the Financing Agreement will initially be guaranteed by Clovis Oncology UK Limited and Clovis Oncology Ireland Limited, secured by a first priority security interest in all the assets of these subsidiary guarantors.

Pursuant to the Financing Agreement, the Company has agreed to certain limitations on its operations, including limitations on making certain restricted junior payments, including payment of dividends, limitation on liens and certain limitations on the ability of its non-Guarantor subsidiaries to own certain assets related to Rubraca and to incur indebtedness.

The Company may terminate the Financing Agreement at any time by paying the Lenders an amount (the <u>Discharge Amount</u>) equal to the sum of (a) (A) the greater of (x) the Borrowed Amount plus (i) if such date is during calendar year 2019, \$35 million or (ii) if such date is during calendar year 2020 or thereafter, \$50 million and (y) (i) if such date is prior to the Repayment Start Date, 1.75 times the Borrowed Amount or (ii) if such date is after the Repayment Start Date, 2.00 times the Borrowed Amount minus (B) the aggregate amount of all quarterly payments previously paid to the Lenders plus (b) all other obligations which have accrued but which have not been paid under the loan documents, including expense reimbursement.

In the event of (i) a change of control of the Company, the Company must pay the Discharge Amount to the Lenders and (ii) an event of default under the Financing Agreement (which includes, among other events, breaches or defaults under or terminations of the Company s material in-license agreements related to Rubraca and defaults under the Company s other material indebtedness), the Lenders have the right to declare the Discharge Amount to be immediately due and payable.

The foregoing descriptions of the terms of the Financing Agreement and Security Agreement, are qualified in their entirety by reference to the provisions of such agreements, which are being filed as exhibits 10.1 and 10.2, respectively, to this Current Report on Form 8-K and are incorporated by reference herein.

The Financing Agreement and the Security Agreement has been included to provide investors and security holders with information regarding its terms. It is not intended to provide any other factual information about the Company or any of its subsidiaries or affiliates. The representations, warranties, and covenants contained in the Financing Agreement and the Security Agreement were made by the parties thereto only for purposes of that agreement and as of specific dates; were solely for the benefit of the parties to such agreement; may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures made for the purposes of allocating contractual risk between the parties to such agreements instead of establishing these matters as facts; and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to investors. Investors should not rely on the representations, warranties, and covenants or any descriptions thereof as characterizations of the actual state of facts or condition of the Company or any of its subsidiaries or affiliates. Additionally, the representations, warranties, covenants, conditions, and other terms of the Financing Agreement and Security Agreement may be subject to subsequent waiver or modification. Moreover, information concerning the subject matter of the representations, warranties, and covenants may change after the date of the Financing Agreement and the Security Agreement, which subsequent information may or may not be fully reflected in the Company s public disclosures.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

(a) The information set forth under Item 1.01 of this Current Report on Form 8-K regarding the Financing Agreement and the Security Agreement is hereby incorporated by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
10.1	Financing Agreement, dated as of May 1, 2019 among Clovis Oncology, Inc. (the Company), certain subsidiaries of the Company named therein, as Guarantors, the Lenders from time to time party thereto, and the Administrative Agent party thereto.
10.2	Pledge and Security Agreement, dated as of May 1, 2019 among each of the Grantors party thereto and the Administrative Agent party thereto.

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 the ATHENA Trial, our expectations regarding the cost of the ATHENA Trial, the potential to out-license Rubraca outside the United States, the expected timing of a potential approval of Rubraca in first line maintenance treatment of ovarian cancer, the total amount of funding that may be available to us under the agreement, our anticipated cash needs, the amount by which the funding under the loan may extend our cash runway and the timing and amount of repayment of the amounts funded under the loan. 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, how our cash needs may be affected by revenues, expenses and other the availability potential financing sources, possible changes to our plans or priorities as we assess data, whether future study results will be consistent with study findings to date, factors affecting the pace of enrollment of ATHENA and the timing of the trial, factors affecting the cost of the ATHENA trial, including pace of enrollment, number of sites activated, length of the trial, how amounts borrowed, future revenues and applicable percentage amounts of quarterly payments affect the overall time for repayment, 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.

May 2, 2019

By: /s/ Paul E. Gross
Name: Paul E. Gross

Title: Executive Vice President, General

Counsel and Chief Compliance Officer

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