FORM 8-K

Current report filing

Filing Date: **2013-01-09** | Period of Report: **2013-01-07**
SEC Accession No. 0001193125-13-007847

(HTML Version on secdatabase.com)

FILER

Clovis Oncology, Inc.
CIK:**1466301**| IRS No.: **900475355** | State of Incorp.:**DE** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **001-35347** | Film No.: **13519875**
SIC: **2834** Pharmaceutical preparations

Mailing Address
2525 28TH STREET
SUITE 100
BOULDER CO 80301

Business Address
2525 28TH STREET
SUITE 100
BOULDER CO 80301
(303) 625-5000

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 7, 2013**

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.)

2525 28th Street, 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:

☐ 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 2.02 Results of Operations and Financial Condition

Although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2012, on January 7, 2013, Clovis Oncology, Inc. (the "Company") issued a press release announcing that the Company had approximately $144.0 million in cash as of December 31, 2012 and expects a cash burn of $53.0 to $57.0 million for the year ending December 31, 2013, which would result in the Company having approximately $90 million in cash as of December 31, 2013. A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

The information contained in this Item 2.02 of Form 8-K is unaudited and preliminary and does not present all information necessary for an understanding of the Company' s financial condition as of December 31, 2012 and its results of operations for the three months and year ended December 31, 2012. The audit of the Company' s consolidated financial statements for the year ended December 31, 2012 is ongoing and could result in changes to the information set forth above.

The information in this Item 2.02 of Form 8-K and the information incorporated by reference herein, including Exhibit 99.1 attached hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Number and Description

99.1 Press Release, dated January 7, 2013.

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.

January 7, 2013

By: /s/ Erle T. Mast

Name: Erle T. Mast

Title: Executive Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release, dated January 7, 2013.

Exhibit 99.1

Clovis Oncology Announces 2013 Objectives and Financial Guidance

January 7, 2013 6:30 AM ET

BOULDER, Colo.−(BUSINESS WIRE)−Jan. 7, 2013−Clovis Oncology, Inc. (NASDAQ: CLVS) today announced anticipated development milestones and financial guidance for 2013. Clovis currently has two clinical development programs and one drug discovery program underway.

CO-1686

A novel, oral, mutant-selective covalent inhibitor of EGFR mutations in non-small cell lung cancer (NSCLC), CO-1686 is currently the subject of an accelerated second-line development program. Clovis anticipates completing the following milestones in 2013 for CO-1686:

- Complete dose escalation portion of Phase I/II study to establish the dose and schedule;
- Initiate expansion cohorts of Phase I/II study to assess efficacy in second-line T790M+ NSCLC patients and in first-line mutant EGFR NSCLC;
- Initiate use of Roche Molecular Systems diagnostic test to identify T790M+ patients; and
- Prepare to initiate pivotal study in second-line T790M+ NSCLC patients in the first half of 2014.

Rucaparib

An oral inhibitor of PARP-1 and PARP-2, rucaparib is being explored in ovarian and breast cancer patients with BRCA mutations and other DNA repair deficiencies. Clovis anticipates completing the following milestones in 2013 for rucaparib:

- Complete dose escalation portion of Phase I/II study to identify the monotherapy dose and schedule;
- Initiate expansion cohort of Phase I/II study to assess efficacy in selected ovarian cancer patients;
- Initiate Phase II biomarker validation in selected ovarian cancer patients to correlate clinical responses with patient genotype and inform the analysis of the pivotal trial;
- Advance development of diagnostic test with Foundation Medicine to identify patients with BRCA mutations and other DNA repair deficiencies most likely to respond to rucaparib;
- Initiate pivotal study of rucaparib as maintenance therapy in selected platinum-sensitive ovarian cancer patients in the second half of 2013.

Mutant c-KIT inhibitor discovery program

During 2012, Clovis entered into a collaboration with Array BioPharma Inc. to discover a novel KIT inhibitor targeting the resistance mutations that occur in the majority of gastrointestinal stromal tumor patients and result in disease progression. This collaboration will continue in 2013 with a goal of identifying a lead compound in late 2013 or early 2014.

Year-End 2012 Cash Position and 2013 Financial Guidance

Clovis ended 2012 with approximately $144.0 million in cash (these results are preliminary and unaudited), which should provide sufficient resources to demonstrate meaningful evidence of efficacy for CO-1686 and rucaparib. Clovis expects a cash burn of $53.0 to $57.0 million for 2013, ending the year with approximately $90.0 million in cash.

About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the U.S., Europe and additional international markets. Clovis Oncology targets development programs at specific subsets of cancer populations, and simultaneously develops diagnostic tools that direct a compound in development to the population that is most likely to benefit from its use. Clovis Oncology is headquartered in Boulder, Colorado, and has additional offices in San Francisco, California and Cambridge, UK.

Forward Looking Statements

To the extent that statements contained in this press release 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. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs or discovery programs, future 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 our clinical development programs for CO-1686 and rucaparib, our discovery program for the mutant cKIT inhibitor, the corresponding development pathways of our companion diagnostics, actions by the FDA, the EMA or other regulatory authorities regarding whether to approve drug applications that may be filed, as well as their decisions regarding drug labeling, and other matters that could affect the availability or commercial potential of our drug candidates or companion diagnostics, including competitive developments. 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 in its reports on Form 10-Q and Form 8-K.

Source: Clovis Oncology

Clovis Oncology

Anna Sussman, 303-625-5022
asussman@clovisoncology.com
or
Breanna Burkart, 303-625-5023
bburkart@clovisoncology.com