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): **August 1, 2018**

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		**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 (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 ☐

Item 2.02 Results of Operations and Financial Condition

On August 1, 2018, Clovis Oncology, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2018. A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

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 August 1, 2018.

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.

August 1, 2018

By: /s/ Patrick J. Mahaffy
Name: Patrick J. Mahaffy
Title: President and Chief Executive Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release, dated August 1, 2018.

Exhibit 99.1

Clovis Oncology Announces Second Quarter 2018 Operating Results

- ***$23.8M in Rubraca® sales for the second quarter of 2018 compared to $14.6M for Q2 2017***
- ***Rubraca approved in U.S. on April 6, 2018 for expanded ovarian cancer maintenance treatment indication***
- ***Rubraca granted Marketing Authorization by European Commission on May 29 for treatment of recurrent ovarian cancer***
- ***EMA validated EU application to include ovarian cancer maintenance treatment in the Rubraca Marketing Authorization; CHMP opinion anticipated by year-end 2018***
- ***Initial TRITON2 data to be presented at ESMO in October; first data presentation of Rubraca in metastatic castration-resistant prostate cancer***
- ***Robust Rubraca monotherapy and combination development programs underway***
- ***Combination studies of lucitanib with each of rucaparib and a PD-(L)1 inhibitor planned Q1 2019***
- ***$20 million charge in Q2 related to a settlement in principle with the S.E.C.***
- ***$682.2 million in cash, cash equivalents and available for sale securities at June 30, 2018***

BOULDER, Colo.--(BUSINESS WIRE)--August 1, 2018--Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended June 30, 2018, and provided an update on the Company's clinical development programs and regulatory and commercial outlook for the second half of 2018.

"We are pleased with the launch of Rubraca in the broader maintenance indication in the U.S. and are preparing for the planned launch in the EU early next year," said Patrick J. Mahaffy, CEO and President of Clovis Oncology. "We look forward to the presentation of the initial data for rucaparib in patients with germline or somatic BRCA mutation-positive metastatic castrate-resistant prostate cancer at ESMO in October, and we are actively advancing multiple combination studies for each of rucaparib and lucitanib."

Second Quarter 2018 Financial Results

Clovis reported net product revenue for Rubraca of $23.8 million for the second quarter of 2018 following the label expansion to include the earlier-line and all-comers ovarian cancer maintenance treatment indication on April 6. The supply of free drug distributed to eligible patients through the Rubraca patient assistance program for the three months ended June 30, 2018 was an additional approximately 25 percent of the overall commercial supply, or the equivalent of $7.9 million in commercial value. In the six months ended June 30, 2018, the supply of this free drug was an additional approximately 24 percent of the overall commercial supply, or the equivalent of $13.4 million in commercial value. The Company expects the free product percentage to continue in the mid to high 20-percent range for the remainder of 2018. Net product revenue for the first quarter of 2018 was $18.5 million, for a total of $42.3 million for the first six months of 2018. Net product revenue for the quarter and first half ended June 30, 2017 was $14.6 million and $21.7 million, following the initial approval and launch of Rubraca in the treatment setting on December 19, 2016.

Clovis had $682.2 million in cash, cash equivalents and available-for-sale securities as of June 30, 2018. Cash used in operating activities was $110.2 million for the second quarter of 2018 and $210.8 million for the first half of 2018, compared with $69.1 million for the second quarter of 2017 and $149.5 million for the first half of 2017. This includes product supply costs of $44.6 million in the second quarter of 2018 and $76.1 million in the first half of 2018 related to Clovis' previously-described plan to build additional inventory in advance of the transition to a new manufacturing facility for Rubraca. Product supply costs are expected to be approximately $10 million for the remainder of 2018. The Company also expects to incur final capital costs for the new manufacturing facility of approximately $8 million in late 2018. Additionally, and also as previously described, Clovis made one-time milestone payments to Pfizer of $58 million in the second quarter of 2018 related to U.S. product approvals in December 2016 and April 2018 and European product approval in May 2018.

Clovis reported a net loss for the second quarter of 2018 of $101.2 million, or ($1.94) per share, and $178.9 million, or a net loss of ($3.48) per share for the first half of 2018. Net loss was $175.4 million, or a net loss of ($3.88) per share for the second quarter of 2017, and $233.8 million, or a net loss of ($5.24) per share for the first half of 2017.

During the second quarter of 2018, Clovis recorded a one-time charge of $20.0 million related to an agreement in principle reached with the S.E.C. that, if approved by the S.E.C. and the U.S. District Court where the settlement is to be filed, would resolve the S.E.C.'s investigation related to rociletinib.

Additionally, the net loss for the six months ended June 30, 2018 also includes a charge of $8.0 million in the first quarter related to a legal settlement. The net loss for the quarter and six months ended June 30, 2017 included a charge of $117.0 million related to a legal settlement.

The adjusted net loss excluding these items was $81.2 million, or ($1.55) per share for the second quarter, and $150.9 million, or ($2.93) per share for the first half of 2018, compared to an adjusted net loss of $58.4 million, or ($1.29) per share for the second quarter, and $116.8 million, or ($2.62) per share for the first half of 2017. Net loss for the second quarter and first half of 2018 included share-based compensation expense of $14.9 million and $26.8 million, compared to $10.7 million and $19.6 million for the comparable periods of 2017.

Clovis had approximately 52.6 million shares of common stock outstanding as of June 30, 2018.

Research and development expenses totaled $52.7 million for the second quarter of 2018 and $96.3 million for the first half of 2018, compared to $33.1 million and $65.6 million for the comparable periods in 2017. Research and development expenses will continue to increase compared to last year as planned Rubraca studies progress.

Selling, general and administrative expenses totaled $44.9 million for the second quarter of 2018 and $84.1 million for the first half of 2018, compared to $36.1 million and $65.4 million for the comparable periods in 2017. Selling, general and administrative expenses will continue to increase compared to last year in support of administrative and commercial activities related to Rubraca in the United States and Europe.

Key Milestones and Objectives for Rubraca

U.S. Approval for Ovarian Cancer Maintenance Treatment Indication

On April 6, the U.S. Food and Drug Administration (FDA) approved Rubraca (rucaparib) tablets for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. FDA granted regular approval for Rubraca in this second, broader and earlier-line indication on a priority review timeline based on positive data from the phase 3 ARIEL3 clinical trial. Biomarker testing is not required for patients to be prescribed Rubraca in this maintenance treatment indication. In addition to granting Rubraca approval in this second indication, the FDA converted the approval of the initial treatment indication from an accelerated to a regular approval.

European Union (EU) Authorization Granted for Recurrent Ovarian Cancer Treatment Indication and Maintenance Treatment Variation Under Review

In late May, the Company announced that the European Commission authorized Rubraca as monotherapy treatment of adult patients with platinum sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum-based chemotherapy, and who are unable to tolerate further platinum-based chemotherapy.

Following the receipt of the initial Marketing Authorization for Rubraca, Clovis submitted a variation to include the maintenance indication, which was validated by the European Medicines Agency (EMA) in early July. The review is underway and an opinion for the maintenance indication from the Committee for Medicinal Products for Human Use (CHMP) is anticipated by the end of 2018. Clovis continues to establish its EU organization to support the planned launch of Rubraca in Europe.

Rubraca Clinical Development

Clovis has a robust clinical development program underway in multiple tumor types, including Clovis-sponsored, partner-sponsored and investigator-initiated trials. The following clinical studies are open for enrollment or are anticipated to open during the next several months:

- The Clovis-sponsored ARIEL4 confirmatory study in the treatment setting is a Phase 3 multicenter, randomized study of Rubraca versus chemotherapy in relapsed ovarian cancer patients with BRCA mutations who have failed two prior lines of therapy. This study is currently enrolling patients.
- The Clovis-sponsored Phase 3 ATHENA study in advanced ovarian cancer in the first-line maintenance treatment setting evaluating Rubraca plus Opdivo® (PD-1 inhibitor), Rubraca, Opdivo and placebo in newly-diagnosed patients who have completed platinum-based chemotherapy. This study, as part of a broad clinical collaboration with Bristol-Myers Squibb, is currently open for enrollment.
- The Clovis-sponsored TRITON3 study, a Phase 3 comparative study in metastatic castration-resistant prostate cancer (mCRPC) enrolling BRCA mutant and ATM mutant (both inclusive of germline and somatic) patients who have progressed on androgen-receptor (AR)-targeted therapy and who have not yet received chemotherapy in the castrate-resistant setting. TRITON3 compares Rubraca to physician's choice of AR-targeted therapy or chemotherapy in these patients. This study is currently enrolling patients.
- The Clovis-sponsored TRITON2 study in mCRPC, a Phase 2 single-arm study in patients with BRCA mutations (inclusive of germline and somatic) and also enrolling patients with deleterious mutations of other homologous recombination (HR) repair genes, including ATM. All patients will have progressed after receiving one line of taxane-based chemotherapy and one or two lines of AR-targeted therapy. This study is currently enrolling patients. The Company plans to present initial data from the ongoing TRITON2 study in a poster discussion session and host an investor/analyst event at ESMO on Sunday, October 21, 2018.
- The Clovis-sponsored single-arm Phase 2 open-label monotherapy study of Rubraca in recurrent, metastatic bladder cancer titled ATLAS: A Study of Rucaparib in Patients with Locally Advanced or Metastatic Urothelial Carcinoma. This study is currently enrolling patients.
- The Phase 1 RUCA-J study, sponsored by Clovis, is a Phase 1 study to identify the recommended dose of rucaparib in Japanese patients, which will enable development of a bridging strategy and potential inclusion of Japanese sites in planned or ongoing global studies. This study is currently enrolling patients.
- The Phase 2, open-label, multi-cohort study evaluating the combination of Rubraca and Opdivo in patients with relapsed, BRCA wild-type ovarian cancer and in patients with locally advanced or metastatic bladder carcinoma. This study is sponsored by Clovis and is expected to begin in the second half of 2018.
- The Phase 3 pivotal study in advanced triple-negative breast cancer (TNBC) to evaluate Opdivo and Rubraca in combination. This study is sponsored by Bristol-Myers Squibb.
- The Phase 2 combination study of Opdivo with Rubraca for the treatment of mCRPC. This study, sponsored by Bristol-Myers Squibb, is being conducted as an arm of a larger sponsored prostate cancer study. This study is currently enrolling patients.
- The Phase 1b combination study of the cancer immunotherapy Tecentriq (atezolizumab; anti-PDL1) and Rubraca for the treatment of ovarian and triple-negative breast cancers. This study is sponsored by Roche and is currently enrolling patients.

Exploratory studies in other tumor types are also underway.

Additionally, in June, the Company announced a planned clinical collaboration with Immunomedics to evaluate the combination of Rubraca and sacituzumab govitecan as a treatment for advanced metastatic triple-negative breast and metastatic urothelial cancers.

Lucitanib Clinical Development

Lucitanib is an oral, potent inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors 1 through 3 (VEGFR1-3), platelet-derived growth factor receptors alpha and beta (PDGFRα/β) and fibroblast growth factor receptors 1 through 3 (FGFR1-3), which was previously evaluated in breast and lung cancers in partnership with Servier. Clovis has received notice from Servier that they will return their ex-US rights (excluding China) for lucitanib later in 2018. Clovis therefore will own global rights (excluding China) to lucitanib. There are no payments from Clovis to Servier related to the return of these ex-US rights.

Lucitanib was originally developed by Clovis and Servier with the hypothesis of activity in FGFR driven tumors; data in breast and lung cancer were insufficient to move the program forward. Recent data for a similar drug that inhibits these same three pathways - when combined with a PD-1 inhibitor - are extremely encouraging and represent a validated and alternative hypothesis for the development of lucitanib in combination with a PD-(L)1 inhibitor, and a Clovis-sponsored combination study is now being planned. Clovis also intends to initiate a study of lucitanib in combination with rucaparib, based on encouraging data of VEGF and PARP inhibitors in combination. Each of these studies is expected to initiate before the end of Q1 2019.

Conference Call Details

Clovis will hold a conference call to discuss Q2 2018 results this afternoon, August 1, at 4:30pm ET. The conference call will be simultaneously webcast on the Company's web site at www.clovisoncology.com, and archived for future review. Dial-in numbers for the conference call are as follows: US participants 866.489.9022, International participants 678.509.7575, conference ID: **9289064.**

About Rubraca (rucaparib)

Rubraca is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in ovarian cancer as well as several additional solid tumor indications. Studies open for enrollment or under consideration include ovarian, prostate, breast, gastroesophageal, pancreatic, lung and bladder cancers. Clovis holds worldwide rights for Rubraca.

In the United States, Rubraca is approved for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Rubraca is also approved in the United States for the treatment of adult patients with deleterious BRCA mutation (germline and/or somatic) associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies and selected for therapy based on an FDA-approved companion diagnostic for Rubraca.

Rubraca is an unlicensed medical product outside of the U.S. and EU.

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, with partners, diagnostic tools intended to 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. Please visit clovisoncology.com for more information.

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. Examples of forward-looking statements contained in this press release include, among others, statements regarding our expectation of timing for review and approval of the MA variation for rucaparib, our expectations for submission of regulatory filings, our plans to present final or interim data on ongoing clinical trials, the timing and pace of commencement of and enrollment in our clinical trials, including those being planned or conducted in collaboration with partners, changes in drug supply timing and costs and other expenses, statements regarding our expectations of the supply of free drug distributed to eligible patients and the final terms and timing of the expected SEC settlement. 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, the uncertainties inherent in the market potential of our approved drug, including the performance of our sales and marketing efforts and the success of competing drugs, the performance of our third-party manufacturers, our clinical development programs for our drug candidates and those of our partners, the corresponding development pathways of our companion diagnostics, the timing of availability of data from our clinical trials and the results, the initiation, enrollment and timing of our planned clinical trials, actions by the FDA, the EMA or other regulatory authorities regarding whether to accept or approve drug applications that may be filed, as well as their decisions regarding drug labeling, reimbursement and pricing, and other matters that could affect the development, availability or commercial potential of our drug candidates or companion diagnostics, and actions and decisions of the SEC and the U.S. District Court where the settlement is to be filed. 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.

CLOVIS ONCOLOGY, INC
CONSOLIDATED FINANCIAL RESULTS
(Unaudited, in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenues:				
Product revenue, net	$ 23,757	$ 14,620	$ 42,279	$ 21,665
Operating expenses:				
Cost of sales - product	4,490	2,730	8,495	3,893
Cost of sales - intangible asset amortization	709	372	1,080	743
Research and development	52,707	33,108	96,250	65,555
Selling, general and administrative	44,864	36,149	84,138	65,373
Total expenses	102,770	72,359	189,963	135,564
Operating loss	(79,013)	(57,739)	(147,684)	(113,899)
Other income (expense):				
Interest expense	(3,581)	(2,598)	(6,216)	(5,178)
Foreign currency (loss) gain	(104)	76	(185)	(83)
Legal settlement loss	(20,000)	(117,000)	(27,975)	(117,000)
Other income	1,475	594	2,883	946
Other income (expense), net	(22,210)	(118,928)	(31,493)	(121,315)
Loss before income taxes	(101,223)	(176,667)	(179,177)	(235,214)
Income tax benefit	33	1,281	292	1,365
Net loss	$ (101,190)	$ (175,386)	$ (178,885)	$ (233,849)
Basic and diluted net loss per common share	$ (1.94)	$ (3.88)	$ (3.48)	$ (5.24)
Basic and diluted weighted-average common shares outstanding	52,223	45,176	51,425	44,610

RECONCILIATION OF GAAP TO NON-GAAP
NET LOSS AND NET LOSS PER SHARE
(Unaudited, in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
GAAP net loss	$ (101,190)	$ (175,386)	$ (178,885)	$ (233,849)
Adjustments:				
Legal settlement loss (1)	20,000	117,000	27,975	117,000
Non-GAAP net loss	$ (81,190)	$ (58,386)	$ (150,910)	$ (116,849)
GAAP net loss per common share	$ (1.94)	$ (3.88)	$ (3.48)	$ (5.24)
Non-GAAP net loss per common share	$ (1.55)	$ (1.29)	$ (2.93)	$ (2.62)

The Company prepares its consolidated financial statements in accordance with U.S. GAAP. This press release also contains non-GAAP measurements of net loss and net loss per common share that the Company believes provide useful supplemental information relating to operating performance and trends and facilitates comparisons with other periods. These non-GAAP financial measures should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP.

Explanation of adjustments:
(1) During the three months ended June 30, 2018, the Company recorded a one-time charge of $20.0 million related to a preliminary agreement reached with the SEC that, if approved by the SEC and U.S. District Court where the settlement is filed, would resolve the SEC's pending investigation.

During the three months ended June 30, 2017, the Company recorded a $117.0 million legal settlement loss related to a stipulation and agreement of settlement entered into between the Clovis Defendants and the plaintiffs to the Consolidated Complaint.

During the three months ended March 31, 2018, the Company recorded a one-time charge of $8.0 million related to an agreement to resolve a potential litigation claim against us and certain of our officers.

CONSOLIDATED BALANCE SHEET DATA

(Unaudited,in thousands)

	June 30, 2018	December 31, 2017
Cash and cash equivalents	$ 468,321	$ 464,198
Available-for-sale securities	213,921	99,533
Working capital	692,002	545,423
Total assets	967,732	735,230
Convertible senior notes	574,335	282,406
Common stock and additional paid-in capital	2,010,364	1,887,249
Total stockholders' equity	312,350	367,636

Other Data

(Unaudited, in thousands)

	Six Months Ended June 30,	
	2018	2017
Net cash used in operating activities	(210,844)	(149,541)
Share Based Compensation Expense	26,768	19,563

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