



Clovis Oncology Announces First Quarter 2018 Operating Results

May 8, 2018

- *\$18.5M in Rubraca® sales for the first quarter of 2018, based on limited third-line BRCA-mutant ovarian cancer treatment label in U.S.*
- *All-comers and earlier-line ovarian cancer maintenance treatment indication approved in U.S. on April 6, 2018*
- *CHMP adopted positive opinion for limited treatment indication in EU on March 23; Marketing Authorization by European Commission anticipated later this month*
- *European maintenance treatment filing for ovarian cancer planned for Q2 2018, potential CHMP opinion by year-end*
- *Initiated potential registrational trial (ATLAS) of Rubraca in advanced bladder cancer during the quarter*
- *Robust Rubraca monotherapy and combination development program underway*
- *Gaining ex-US rights excluding China for lucitanib from Servier; combination studies with each of rucaparib and a PD(L)-1 inhibitor planned*
- *\$850 million in adjusted cash, cash equivalents and available for sale securities at March 31, 2018 as adjusted for the April 2018 financing proceeds of \$386 million*

BOULDER, Colo.--(BUSINESS WIRE)--May 8, 2018-- [Clovis Oncology](#), Inc. (NASDAQ:CLVS) reported financial results for the quarter ended March 31, 2018, and provided an update on the Company's [clinical development programs](#) and regulatory and commercial outlook for 2018.

"We were very pleased to receive the expanded maintenance treatment indication for Rubraca in the U.S. in early April, and while it is early days in the launch, we are receiving very positive feedback to the broader and earlier-line label from clinicians," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We are well positioned now with a strong balance sheet and a robust clinical development program for Rubraca, initiating new Clovis-sponsored single-arm studies in ovarian and bladder cancers with Opdivo by year-end, and looking forward to presenting initial data from TRITON2 in prostate cancer at ESMO in October. Finally, we are enthusiastic about initiating a global clinical development program for lucitanib, including multiple combination studies."

First Quarter 2018 Financial Results

Clovis reported net product revenue for Rubraca of \$18.5 million for the first quarter of 2018. During the first quarter, the supply of free drug distributed to eligible patients through the Rubraca patient assistance program was approximately 22 percent of overall commercial supply. This would have represented an additional \$5.1 million in commercial value for the quarter. We expect the supply of free drug to remain at this percentage or slightly higher for the foreseeable future. Net product revenue for the quarter ended March 31, 2017 was \$7.0 million, following the initial approval and launch of Rubraca in the treatment setting on December 19, 2016.

Clovis had \$463.8 million in cash, cash equivalents and available-for-sale securities as of March 31, 2018. In April 2018, Clovis raised net proceeds of \$94.0 million through an offering of 1.8 million shares of common stock and \$292 million aggregate principal amount of 1.25% convertible senior notes due 2025. The net proceeds from these offerings were \$386.0 million, after deducting underwriting discounts and commissions, and offering expenses.

Clovis reported a net loss for the first quarter of 2018 of \$77.7 million, or (\$1.54) per share. The net loss for the first quarter of 2017 was \$58.5 million, or (\$1.33) per share. Net loss for the first quarter of 2018 included share-based compensation expense of \$11.9 million, compared to \$8.9 million for the first quarter of 2017.

Cash used in operating activities was \$100.6 million for the first quarter of 2018, compared with \$80.4 million in the first quarter of 2017. This includes product supply costs of \$31.5 million in the first quarter of 2018, compared to \$18.2 million for the first quarter of 2017. Product supply costs will be approximately \$44 million in the second quarter of 2018 and will be approximately \$10 million for the remainder of 2018. These costs reflect Clovis' plan to build additional inventory in advance of the transition to a new manufacturing facility for Rubraca. The Company will also incur final capital costs for the new manufacturing facility of approximately \$8 million in late 2018 as well. Additionally, Clovis will make one-time milestone payments to Pfizer of \$38 million in the second quarter of 2018 related to product approvals in December 2016 and April 2018 and potentially an additional \$20 million milestone payment in the second quarter if the Rubraca Marketing Authorization in Europe is granted prior to June 15, 2018.

Clovis had approximately 50.7 million shares of common stock outstanding as of March 31, 2018.

Research and development expenses totaled \$43.5 million for the first quarter of 2018, compared to \$32.4 million for the first quarter 2017. Research and development expenses will continue to increase compared to last year as planned Rubraca studies progress.

Selling, general and administrative expenses totaled \$39.3 million for the first quarter of 2018, compared to \$29.2 million for the first quarter in 2017. Selling, general and administrative expenses will continue to increase compared to last year in support of 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) Treatment Approval Anticipated in Q2 2018

In late March, the Company announced that the European Union's (EU) European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the granting of a conditional marketing authorization for 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. Clovis continues to anticipate the grant of the Marketing Authorization by the European Commission to follow in Q2 2018, and plans to submit a variation to the Marketing Authorization for the maintenance treatment indication, with the CHMP opinion for maintenance anticipated by the end of 2018. Clovis continues to establish its EU organization to support the planned launch of Rubraca in Europe.

Also during the quarter, the Company initiated an early access program in Europe for rucaparib for treatment and as maintenance therapy in recurrent ovarian cancer. The program, to be known as the Rucaparib Access Program (RAP), will enable participation from certain countries in Europe, where permitted by applicable rules, procedures and regulatory authorities. The RAP protocol allows for rucaparib treatment of an individual patient with third-line or greater BRCA mutant epithelial, fallopian tube, or primary peritoneal ovarian cancer who has platinum-sensitive disease and is unable to tolerate further platinum-based chemotherapy or has platinum-resistant disease and needs treatment with single agent rucaparib. The RAP protocol will also provide access to rucaparib for maintenance therapy of an individual patient with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who has received at least two prior platinum-based treatment regimens, has platinum-sensitive disease, and is in a complete or partial response to the most recent platinum-based regimen. In all cases, the patient must have a special clinical need that cannot be met by current licensed available medicines. Patients must be ineligible for Clovis' ARIEL4 clinical trial or unable to access a participating ARIEL4 site to qualify for Clovis' early access program. Questions or inquiries regarding the RAP should be directed to rucaparibaccessEU@caligorr.com.

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 expected to begin in the first half of 2018.
- The Clovis-sponsored TRITON3 study, a Phase 3 comparative study in mCRPC enrolling BRCA mutant and ATM mutant (both inclusive of germline and somatic) patients who have progressed on AR-targeted therapy and who have not yet received chemotherapy in the castrate-resistant setting is also open for enrollment. 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 enrolling patients with BRCA mutations and ATM mutations (both inclusive of germline and somatic) or other deleterious mutations in other homologous recombination (HR) repair genes. All patients will have progressed after receiving one line of taxane-based chemotherapy and one or two lines of androgen-receptor (AR) targeted therapy. This study is currently enrolling patients. The Company plans to present initial data from the ongoing TRITON2 study at ESMO in October 2018, pending abstract acceptance.
- A 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, initiated during the quarter with the first patient dosed with rucaparib in Japan. The Phase 1 study seeks 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.
- A 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 who are ineligible for treatment with cisplatin. 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.

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 (PDGFR α/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 Q1 2018 results this afternoon, May 8, 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: **4198438**.

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.

[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 MAA for rucaparib for the treatment and the maintenance treatment indications, 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 costs and other expenses and statements regarding our expectations of the supply of free drug distributed to eligible patients. 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 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. 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 March 31,	
	2018	2017
Revenues:		
Product revenue	\$ 18,523	\$ 7,045
Operating expenses:		
Cost of sales - product	4,006	1,163
Cost of sales - intangible asset amortization	372	372
Research and development	43,543	32,447
Selling, general and administrative	39,274	29,224
Total expenses	87,195	63,206
Operating loss	(68,672)	(56,161)
Other income (expense):		
Interest expense	(2,635)	(2,581)
Foreign currency loss	(81)	(159)
Legal settlement loss	(7,975)	-
Other income	1,409	354
Other income (expense), net	(9,282)	(2,386)
Loss before income taxes	(77,954)	(58,547)
Income tax benefit	260	83
Net loss	\$ (77,694)	\$ (58,464)

Basic and diluted net loss per common share	\$ (1.54)	\$ (1.33)
Basic and diluted weighted-average common shares outstanding	50,602	44,039

RECONCILIATION OF GAAP TO NON-GAAP

ADJUSTED CASH

(in thousands)

	March 31, 2018	
Cash, cash equivalents and available-for-sale securities	\$	463,811
April 2018 financing proceeds		386,000
Adjusted cash		849,811

The Company prepares its consolidated financial statements in accordance with U.S. GAAP. This press release also contains non-GAAP measurements of adjusted cash 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.

CONSOLIDATED BALANCE SHEET DATA

(Unaudited, in thousands)

	March 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 374,114	\$ 464,198
Available-for-sale securities	89,697	99,533
Working capital	474,231	545,423
Total assets	678,924	735,230
Convertible senior notes	282,732	282,406
Common stock and additional paid-in capital	1,899,675	1,887,249
Total stockholders' equity	306,236	367,636

Other Data

(Unaudited, in thousands)

	Three Months Ended March 31,	
	2018	2017
Net cash used in operating activities	(100,635)	\$ (80,439)
Share Based Compensation Expense	11,913	\$ 8,947

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