Clovis Oncology Announces Q2 2016 Operating Results and Corporate Update

August 8, 2016 4:05 PM ET

- *Rucaparib NDA submission completed in late June for treatment of patients with advanced ovarian cancer with deleterious BRCA mutated tumors*
- *FDA decision on filing and determination of PDUFA date is anticipated in late August*
- *Rucaparib MAA submission on track for Q4 2016*
- *Rucaparib NDA dataset accepted for an oral presentation at ESMO 2016 Congress in October*
- *Clovis preparing for potential U.S. commercial launch of rucaparib*
- *ARIEL3 pivotal rucaparib maintenance study enrollment completed; data now expected in Q4 2017*
- *$378.5 million in cash, cash equivalents and available-for-sale securities at the end of Q2 2016*

BOULDER, Colo.--(BUSINESS WIRE)--Aug. 8, 2016-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended June 30, 2016, and provided an update on the Company's clinical development programs and regulatory outlook for the remainder of 2016.

"We are pleased to have completed the submission of our NDA for rucaparib in the treatment of advanced ovarian cancer in late June," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We continue to focus on our broader clinical development program for rucaparib, and are actively preparing for a potential U.S. launch of rucaparib."

Second Quarter 2016 Financial Results

Clovis had $378.5 million in cash, cash equivalents and available-for-sale securities as of June 30, 2016. Cash used in operating activities was $68.0 million for the second quarter of 2016 and $151.7 million for the first half of 2016, compared with $57.2 million and $105.6 million for the comparable periods of 2015. Cash used in operating activities in the second quarter of 2016 was down $15.7 million, or 18.8 percent compared to the first quarter of 2016. Clovis had approximately 38.5 million outstanding shares of common stock as of June 30, 2016.

Clovis reported a net loss of $129.3 million, or ($3.37) per share, for the second quarter of 2016 and $212.7 million or ($5.54) per share for the first half of 2016. Net loss for the second quarter of 2016 included share-based compensation expense of $9.5 million and $20.5 million for the first half of 2016, compared to $8.4 million and $17.1 million for the comparable periods of 2015.

Notably, the net loss for the second quarter and first half of 2016 includes a net expense non-cash impact of $49.9 million relating to the lucitanib product rights recorded in 2013 in connection with the Company's acquisition of Ethical Oncology Science S.p.A. (EOS), comprised of a $104.5 million non-cash expense for the impairment of the intangible asset, a $25.5 million non-cash expense credit for the reduction in the fair value of the contingent purchase consideration liability and a $29.2 million related non-cash income tax benefit. The adjusted net loss excluding these items was $79.4 million or ($2.07) per share in the second quarter of 2016 and $162.8 million or ($4.24) per share for the first half of 2016. The net loss for the second quarter of 2015 was $71.5 million or ($2.10) per share, and $134.7 million or ($3.96) per share for the first half of 2015.

Research and development expenses totaled $67.7 million for the second quarter of 2016, and $142.3 million for the first half of 2016, compared to $60.4 million and $117.1 million for the comparable periods in 2015. The year-over-year increase in expenses is primarily due to increased development activities for the rucaparib program and increased personnel-related expenses, partially offset by lower expenses related to clinical development activities for rociletinib. In addition, research and development expenses in the second quarter of 2016 were down $6.9 million, or 10.2 percent compared to the first quarter of 2016.

General and administrative expenses totaled $9.6 million for the second quarter of 2016, and $19.4 million for the first half of 2016, compared to $7.2 million and $14.0 million for the comparable periods in 2015. The increase year over year is

primarily due to higher legal expense, personnel costs for employees engaged in general and administrative activities and consulting fees.

Clovis expects cash used in operating activities for 2016 will total approximately $294 - $309 million, and to end the year with approximately $220 - $235 million in cash, cash equivalents and available-for-sale securities. The Company anticipates being able to continue to fund operations into 2018 from currently available cash, cash equivalents and available-for-sale securities.

As noted above, in the second quarter of 2016 Clovis recorded a non-cash impairment charge of $104.5 million to reflect a reduction in the estimated fair value of the intangible asset related to lucitanib. This reduction in fair value was the result of Clovis and its development partner's decision to discontinue enrollment in the ongoing trials and any future development of lucitanib for breast cancer. During the fourth quarter of 2015, Clovis and its development partner discontinued the development of lucitanib for lung cancer. The Company expects to make a decision regarding the future development, if any, of lucitanib during the next several quarters.

In connection with its acquisition of EOS, Clovis is obligated to pay additional consideration to the former EOS shareholders if certain future regulatory and sales milestones for lucitanib are achieved. The estimated fair value of these contingent payments is recorded as a liability on the Company's balance sheet. During the second quarter of 2016, Clovis recorded a $25.5 million reduction to zero in the fair value of the contingent consideration liability due to the uncertainty of achieving any of the milestones. This reduction is included as a non-cash credit to operating expenses in Clovis' 2016 results of operations. There are no remaining lucitanib-related liabilities on the Company's balance sheet.

2016 Key Milestones and Objectives for Rucaparib

During the second quarter of 2016, Clovis completed the submission of its New Drug Application (NDA) regulatory filing to the U.S. Food and Drug Administration (FDA) for rucaparib for the monotherapy treatment of patients with advanced ovarian cancer with deleterious BRCA-mutated tumors (inclusive of both germline and somatic BRCA mutations) previously treated with multiple prior therapies. Rucaparib was granted Breakthrough Therapy designation by the FDA in April 2015. The Company expects the FDA to provide notification in late August whether they have accepted the rucaparib NDA filing for review, and provide a PDUFA date in the event the filing is accepted.

Foundation Medicine, Clovis' companion diagnostic partner, has submitted a Premarket Approval (PMA) application for its diagnostic assay designed to identify both germline and somatic BRCA mutations with the FDA. The timing of the submission is expected to allow for regulatory approval of the companion diagnostic at substantially the same time that rucaparib could be approved.

In addition, the Company intends to submit its Marketing Authorization Application (MAA) for rucaparib to the European Medicines Agency for a comparable ovarian cancer treatment indication in Q4 2016.

Clovis has completed enrollment in the ARIEL3 Phase 3 randomized maintenance study, with data expected to be available in Q4 2017. Pending positive data, the Company intends to follow up with a supplemental NDA for second-line maintenance therapy in women with ovarian cancer who have responded to platinum based therapy.

During the second quarter Clovis entered into a clinical trial collaboration with Genentech, a member of the Roche Group, to evaluate a novel combination therapy of Genentech's cancer immunotherapy atezolizumab (MPDL3280A; anti-PDL1) and rucaparib for the treatment of gynecological cancers, with a focus on ovarian cancer. The Phase 1b trial is expected to begin screening patients in Q1 2017.

Also during the fourth quarter of 2016, Clovis intends to initiate the ARIEL4 confirmatory study in advanced BRCA mutant (inclusive of germline and somatic) ovarian cancer and an investigator-sponsored study evaluating rucaparib and bevacizumab in combination as a first-line maintenance therapy for advanced ovarian cancer.

Prostate Cancer Development Plan

Clovis intends to initiate two registration studies of rucaparib in the metastatic castrate-resistant prostate cancer (mCRPC) setting.

The Phase 2 single-arm study is expected to include patients with BRCA mutations and ATM mutations (both inclusive of germline and somatic) or other deleterious mutations in other homologous recombination (HR) repair genes and all patients will have progressed after receiving one line of taxane-based chemotherapy and one or two lines of androgen-receptor (AR) targeted therapy, in the castration-resistant setting. The planned primary end points are radiologic overall response rate in patients with measurable disease and PSA response rate in patients who do not have measurable disease. Clovis intends to initiate this trial during the fourth quarter of 2016.

The Phase 3 comparative study is planned to include 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. The Phase 3 study will compare rucaparib to physician's choice of AR-targeted therapy or chemotherapy in these patients. The intended primary end point is radiologic progression-free survival. Clovis intends to initiate this trial during the first quarter of 2017.

An abstract based on the ovarian NDA dataset has been accepted for an oral presentation at the ESMO 2016 Congress in October 2016.

Conference Call Details

Clovis will hold a conference call to discuss second quarter 2016 results this afternoon, August 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: **56962872**.

About Rucaparib

Rucaparib is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed for advanced ovarian cancer. Rucaparib was granted Breakthrough Therapy designation by the FDA in April 2015; and in late June 2016, Clovis completed the submission of its NDA to the FDA. Additionally, rucaparib is being developed as maintenance therapy in the ARIEL3 trial for patients with tumors with BRCA mutations and other DNA repair deficiencies beyond BRCA, including those with high genomic loss of heterozygosity (LOH) commonly referred to as "BRCA-like." Data from ARIEL3 are expected in Q4 2017, which is expected to be followed by the submission of a sNDA for a second line or later maintenance indication. Clovis is also exploring rucaparib in other solid tumor types with significant BRCA and BRCA-like populations, including prostate, breast and gastroesophageal cancers. Clovis holds worldwide rights for rucaparib.

About Lucitanib

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). Clovis, which holds exclusive U.S. and Japanese rights, is collaborating with its development partner Les Laboratoires Servier (Servier) on the global clinical development of lucitanib outside of China.

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.

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, 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 our drug candidates, 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 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
(in thousands, except per share amounts)

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2016	**2015**	**2016**	**2015**
Revenues:				
License and milestone revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	67,729	60,368	142,337	117,118
General and administrative	9,552	7,204	19,379	13,955
Acquired in-process research and development	300	-	300	-
Impairment of intangible asset	104,517	-	104,517	-
Change in fair value of contingent purchase consideration	(25,452)	764	(24,936)	1,488
Total expenses	156,646	68,336	241,597	132,561
Operating loss	(156,646)	(68,336)	(241,597)	(132,561)
Other income (expense):				
Interest expense	(2,106)	(2,097)	(4,210)	(4,172)
Foreign currency gains (losses)	183	(1,142)	(368)	2,105
Other income	196	62	221	73
Other expense, net	(1,727)	(3,177)	(4,357)	(1,994)
Loss before income taxes	(158,373)	(71,513)	(245,954)	(134,555)
Income tax benefit (expense)	29,059	(18)	33,240	(120)
Net loss	$ (129,314)	$ (71,531)	$ (212,714)	$ (134,675)

Basic and diluted net loss per common share	$ (3.37)	$ (2.10)	$ (5.54)	$ (3.96)
Basic and diluted weighted average common shares outstanding	38,389	34,088	38,375	34,049

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
GAAP net loss	$ (129,314)	$ (71,531)	$ (212,714)	$ (134,675)
Adjustments:				
Impairment of intangible asset (1)	104,517	-	104,517	-
Change in fair value of contingent purchase consideration (2)	(25,452)	-	(25,452)	-
Income tax benefit (1)	(29,160)	-	(29,160)	-
Non-GAAP net loss	$ (79,409)	$ (71,531)	$ (162,809)	$ (134,675)
GAAP net loss per common share	$ (3.37)	$ (2.10)	$ (5.54)	$ (3.96)
Non-GAAP net loss per common share	$ (2.07)	$ (2.10)	$ (4.24)	$ (3.96)

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, 2016, the Company recorded a $104.5 million non-cash impairment charge to the intangible asset related to the lucitanib product rights initially recorded in 2013 in connection with the acquisition of Ethical Oncology Science, S.p.A (EOS). The Company also recorded a $29.2 million tax benefit associated with this charge. This adjustment removes the net of tax effect of this charge from our net loss.

(2) During the three months ended June 30, 2016, the Company recorded a $25.5 million non-cash credit to operating expenses to reflect the reduction in the fair

value of the contingent purchase consideration liability, also associated with the Company's acquisition of EOS. This adjustment, which excludes the normal
accretion of the liability, removes the effect of this expense credit from our net loss.

CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	June 30, 2016	December 31, 2015
Cash and cash equivalents	$ 228,379	$ 278,756
Available-for-sale securities	150,122	249,832
Working capital	326,681	464,125
Total assets	467,985	713,386
Convertible senior notes	280,501	279,885
Common stock and additional paid-in capital	1,152,502	1,130,016
Total stockholders' equity	112,832	300,650

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