Clovis Oncology Announces Q3 2016 Operating Results and Corporate Update

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- *Rucaparib New Drug Application (NDA) accepted for Priority Review in the treatment of advanced BRCA-mutant ovarian cancer; PDUFA date February 23, 2017*
- *Rucaparib MAA submission submitted this week*
- *Clovis commercial and medical affairs organizations preparing for potential U.S. commercial launch of rucaparib*
- *ARIEL3 pivotal rucaparib maintenance study enrollment completed; data expected in 2H 2017*
- *Rucaparib development plan in place; new clinical studies in ovarian, prostate, gastroesophageal cancers planned to initiate this quarter*
- *$318.8 million in cash, cash equivalents and available-for-sale securities at the end of Q3 2016*

BOULDER, Colo.--(BUSINESS WIRE)--Nov. 3, 2016-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended September 30, 2016, and provided an update on the Company's clinical development programs and regulatory outlook for the remainder of 2016.

"We are actively preparing for a U.S. launch of rucaparib pending FDA's decision on our NDA, and we have completed our Marketing Authorization Application submission seeking European approval for rucaparib," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "Importantly, we remain focused on exploring rucaparib more broadly, and expect several studies to initiate this quarter, including the TRITON2 study in prostate cancer, the ARIEL4 confirmatory study in ovarian cancer and investigator-sponsored studies exploring rucaparib as maintenance therapy in gastroesophageal cancer and also in combination with bevacizumab in ovarian cancer."

Third Quarter 2016 Financial Results

Clovis had $318.8 million in cash, cash equivalents and available-for-sale securities as of September 30, 2016. Cash used in operating activities was $60.3 million for the third quarter of 2016 and $212.0 million for the first nine months of 2016, compared with $71.7 million and $177.4 million for the comparable periods of 2015. Clovis had approximately 38.6 million outstanding shares of common stock as of September 30, 2016.

Clovis reported a net loss of $65.7 million, or ($1.70) per share, for the third quarter of 2016 and $278.4 million or ($7.24) per share for the first nine months of 2016. The net loss for the third quarter of 2015 was $98.6 million or ($2.62) per share and $233.3 million or ($6.62) per share for the first nine months of 2015. Net loss for the third quarter of 2016 included share-based compensation expense of $9.2 million and $29.7 million for the third quarter and the first nine months of 2016, respectively, compared to $12.4 million and $29.5 million for the comparable periods of 2015.

Notably, the net loss for the first nine months 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 $228.5 million or ($5.95) per share for the first nine months of 2016.

Research and development expenses totaled $54.3 million for the third quarter of 2016, and $196.7 million for the first nine months of 2016, compared to $76.1 million and $193.3 million, respectively, for the comparable periods in 2015. The decrease in expenses for the third quarter is primarily due to decreased development activities for rociletinib compared to the prior year partially offset by higher expenses associated with rucaparib development programs and launch preparation. The increase in expenses for the nine-month period is primarily due to increased development activities for the rucaparib program, launch preparation and increased personnel-related expenses, partially offset by lower expenses related to decreased clinical development activities for rociletinib.

General and administrative expenses totaled $9.2 million for the third quarter of 2016, and $28.5 million for the first nine months of 2016, compared to $8.3 million and $22.3 million for the comparable periods in 2015. The increase year over year is primarily due to higher legal expense and personnel costs for employees engaged in general and administrative activities.

Clovis expects cash used in operating activities for 2016 will total approximately $276 - $286 million, and to end the year with approximately $245 - $255 million in cash, cash equivalents and available-for-sale securities. This change to cash guidance is primarily related to the recent amendment to the worldwide license agreement with Pfizer for rucaparib which allows Clovis the option to defer payment of the milestone payments payable upon U.S. Food and Drug Administration (FDA) approval of a first NDA in the US and European Medicines Authority (EMA) approval of a first Marketing Authorization Application (MAA) in EU to a date that is 18 months after the date of achievement of such milestones, in exchange for certain higher payments related to the achievement of such milestones. The Company anticipates being able to continue to fund operations into 2018 from currently available cash, cash equivalents and available-for-sale securities.

2016 Key Milestones and Objectives for Rucaparib

During the third quarter of 2016, the rucaparib NDA regulatory filing was accepted by FDA for accelerated approval and granted priority review status with a PDUFA date of February 23, 2017. The application is for rucaparib as monotherapy treatment of patients with advanced ovarian cancer with deleterious BRCA-mutated tumors previously treated with two or more chemotherapies. Tumor BRCA mutations include germline and/or somatic mutations. Rucaparib was granted Breakthrough Therapy designation by the FDA in April 2015.

Foundation Medicine, Clovis' companion diagnostic partner, has submitted a Premarket Approval (PMA) application for its tissue-based diagnostic assay designed to identify tumor BRCA mutations, including germline and somatic 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 submitted an MAA for rucaparib to the European Medicines Agency for a comparable ovarian cancer treatment indication earlier this week.

In October, in support of the potential U.S. commercial launch of rucaparib, we announced the signing of a long-term manufacturing agreement with Lonza, our current manufacturer. We expect that this new agreement for a dedicated manufacturing line will provide security of supply and reduce our cost of goods over time.

Clovis has completed enrollment in the ARIEL3 Phase 3 randomized maintenance study, with data expected to be available in 2H 2017. Pending positive data, the Company intends to follow up with a supplemental NDA (sNDA) for second-line maintenance therapy in women with ovarian cancer who have responded to platinum based therapy.

At the 2016 ESMO Congress in early October, the primary efficacy and safety data from the NDA dataset for rucaparib were presented in an oral session, including the following highlights:

- The RECIST ORR (objective response rate as assessed by the investigator, which includes complete and partial responses) in the 106 patients evaluable for efficacy was 54% (95% CI: 43.8-63.5).
- Duration of response by investigator assessment in the efficacy population was 9.2 months (95% CI: 6.6-11.7 months).
- The most common treatment-emergent adverse events (AEs) (all grades) reported in ≥20 percent of patients in the safety population (n=377) included nausea (77%), asthenia/fatigue (77%), vomiting (46%), anemia (44%), increased ALT/AST (41%) and constipation (40%). The most common Grade 3/4 treatment-emergent AEs reported in ≥10 percent of patients were anemia (25%), asthenia/fatigue (11%) and ALT/AST elevations (11%).

Several clinical studies, including both Clovis-sponsored and investigator-initiated trials, recently initiated or are planned to begin enrolling patients during the fourth quarter. These include the Clovis-sponsored ARIEL4 confirmatory study in

advanced BRCA mutant (inclusive of germline and somatic) ovarian cancer; an investigator-sponsored study evaluating rucaparib and bevacizumab in combination as a first-line maintenance therapy for advanced ovarian cancer; the investigator-initiated RUBY study in women with breast cancer whose tumors have a somatic BRCA mutation or homologous recombination deficient (HRD) signature other than a known germline BRCA mutation; the investigator-initiated PLATFORM study in gastroesophageal cancer in the first-line maintenance setting; and the Clovis-sponsored TRITON2 (**T**rial of **R**ucapar**i**b in Pros**t**ate Indicati**on**s) study in metastatic castrate-resistant prostate cancer (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 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.

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 planned to initiate during the first quarter of 2017. TRITON3 will compare rucaparib to physician's choice of AR-targeted therapy or chemotherapy in these patients. Also during the first quarter of 2017, the Phase 1b combination study of Genentech's cancer immunotherapy Tecentriq (atezolizumab; anti-PDL1) and rucaparib for the treatment of gynecological cancers, with a focus on ovarian cancer, is expected to have the first patient initiated (FPI).

Conference Call Details

Clovis will hold a conference call to discuss third quarter 2016 results this afternoon, November 3, 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: **10466069**.

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 its NDA submission for the treatment of advanced ovarian cancer is currently under active review with the FDA. The MAA submission in Europe for a comparable ovarian cancer indication completed during the fourth quarter of 2016. 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 2H 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 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 September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Revenues:				
License and milestone revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	54,338	76,138	196,675	193,256
General and administrative	9,162	8,331	28,541	22,286
Acquired in-process research and development	500	12,000	800	12,000
Impairment of intangible asset	-	-	104,517	-
Change in fair value of contingent purchase consideration	-	783	(24,936)	2,271
Total expenses	64,000	97,252	305,597	229,813
Operating loss	(64,000)	(97,252)	(305,597)	(229,813)
Other income (expense):				
Interest expense	(2,108)	(2,099)	(6,318)	(6,271)
Foreign currency gains (losses)	(66)	(101)	(434)	2,004
Other income	252	179	473	252
Other expense, net	(1,922)	(2,021)	(6,279)	(4,015)
Loss before income taxes	(65,922)	(99,273)	(311,876)	(233,828)
Income tax benefit	227	628	33,467	508
Net loss	$ (65,695)	$ (98,645)	$ (278,409)	$ (233,320)
Basic and diluted net loss per common share	$ (1.70)	$ (2.62)	$ (7.24)	$ (6.62)
Basic and diluted weighted average common shares outstanding	38,538	37,613	38,429	35,252

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
GAAP net loss	$ (65,695)	$ (98,645)	$ (278,409)	$ (233,320)
Adjustments:				
Impairment of intangible asset (1)	-	-	104,517	-
Change in fair value of contingent purchase consideration (2)	-	-	(25,452)	-
Income tax benefit (1)	-	-	(29,160)	-
Non-GAAP net loss	$ (65,695)	$ (98,645)	$ (228,504)	$ (233,320)
GAAP net loss per common share	$ (1.70)	$ (2.62)	$ (7.24)	$ (6.62)
Non-GAAP net loss per common share	$ (1.70)	$ (2.62)	$ (5.95)	$ (6.62)

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, 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)

	September 30, 2016	December 31, 2015
Cash and cash equivalents	$ 243,724	$ 278,756
Available-for-sale securities	75,054	249,832
Working capital	272,278	464,125

Total assets	398,624	713,386
Convertible senior notes	280,813	279,885
Common stock and additional paid-in capital	1,162,363	1,130,016
Total stockholders' equity	57,038	300,650

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Source: Clovis Oncology, Inc.

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