Clovis Oncology Announces 2015 Operating Results

February 25, 2016 4:06 PM ET

- *Rociletinib NDA scheduled for discussion at ODAC panel on April 12 with a June 28 PDUFA date*
- *Rucaparib NDA submission for treatment of advanced ovarian cancer expected to complete Q2 2016*

BOULDER, Colo.--(BUSINESS WIRE)--Feb. 25, 2016-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for its quarter and year ended December 31, 2015, and provided an update on the Company's clinical development programs and regulatory outlook for 2016.

"2016 has the potential to be a very transformational year for Clovis," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We are preparing for the rociletinib ODAC panel in April ahead of our June 28, 2016 PDUFA date, as well as the planned NDA submission of rucaparib during the second quarter. Our U.S. commercial and medical affairs organizations are in place as we work toward the potential launch of two oncology drugs in the U.S. within the next twelve months."

2015 Financial Results

Clovis had $528.6 million in cash, cash equivalents and available-for-sale securities as of December 31, 2015. Cash used in operating activities was $75.7 million for the fourth quarter of 2015, and $253.1 million for the year ending December 31, 2015, inclusive of $12.0 million in rociletinib milestone payments made in the third quarter of 2015.

Clovis reported a net loss for the fourth quarter of 2015 of $119.5 million ($3.12) per share, and $352.9 million ($9.79) per share for the year ended December 31, 2015. Importantly, the net loss for the fourth quarter and full year 2015 includes a $89.6 million non-cash charge ($61.0 million net of the related income tax benefit) for the impairment of the intangible asset relating to the lucitanib product rights recorded in 2013 in connection with the Company's acquisition of Ethical Oncology Science S.p.A. (EOS) and a $26.9 million non-cash expense credit for the reduction in the fair value of the contingent purchase considerations liability, also related to the EOS acquisition. The adjusted net loss excluding these items was $85.4 million ($2.23 per share) in the fourth quarter of 2015 and $318.8 million ($8.85 per share) for the year ended December 31, 2015. The net loss for the fourth quarter of 2014 was $54.9 million ($1.62 per share) and $160.0 million ($4.72 per share) for the year ended December 31, 2014.

Research and development expenses totaled $76.0 million for the fourth quarter of 2015 and $269.3 million for the full year 2015, compared to $50.1 million for the fourth quarter and $137.7 million for the full year 2014. The increase in expenses for both periods is due to the significantly expanded clinical development activities for rociletinib and rucaparib, increased commercial product planning costs associated with the potential approval and launch of rociletinib, and increased personnel-related expenses associated with the hiring of additional staff to support the Company's expanded activities, including the hiring of the U.S. commercial and medical affairs organizations.

General and administrative expenses totaled $8.2 million for the fourth quarter of 2015 and $30.5 million for the full year 2015, compared to $5.6 million for the fourth quarter and $21.5 million for the full year 2014. The increase year over year is primarily due to personnel costs for employees engaged in general and administrative activities, increased facility costs and higher professional service fees.

As noted above, in the fourth quarter of 2015 Clovis recorded a non-cash impairment charge of $89.6 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 our and our development partner's decision to terminate the development of lucitanib for lung cancer, as well as updates to the probability-weighted discounted cash flow assumptions for the breast cancer indication.

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 fourth quarter of 2015, Clovis recorded a $26.9 million reduction in the fair value of the contingent consideration liability due to a change in the estimated probability-weighted future milestone payments. This reduction is included as a non-cash credit to operating expenses in Clovis' 2015 results of operations.

There was no acquired in-process research and development expense for the fourth quarter of 2015, and $12.0 million for the full year 2015, with none reported in the fourth quarter of 2014 and $8.8 million for the full year 2014. During the third quarter of 2015, the Company made milestone payments totaling $12.0 million upon the acceptance of the NDA and MAA submissions for rociletinib by the U.S. FDA and European Medicines Agency, respectively. In the first quarter of 2014, the Company recorded milestone revenue of $13.6 million received pursuant to our collaboration and license agreement for lucitanib and also recognized charges for acquired in-process research and development expense totaling $8.4 million associated with milestone payments incurred for rociletinib and lucitanib.

Operating expenses for the fourth quarter of 2015 and year ended December 31, 2015 include share-based compensation expense totaling $10.9 million and $40.4 million, respectively.

2016 Key Milestones and Objectives

Highlights of planned or completed objectives for each product follow:

Rociletinib

Rociletinib is an investigational therapy for the treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation. The U.S. Food and Drug Administration (FDA) has accepted Clovis' New Drug Application (NDA) for rociletinib and has granted it priority review status with a Prescription Drug User Fee Act (PDUFA) action date of June 28, 2016. In addition, the European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) for rociletinib. Both reviews are ongoing.

The Company is preparing for its scheduled Oncologic Drugs Advisory Committee (ODAC) panel discussion regarding the rociletinib NDA on April 12, 2016.

During the first quarter the Company initiated a Phase 1b/2 trial of rociletinib in combination with investigational cancer immunotherapy atezolizumab (MPDL3280A; anti-PD-L1 antibody). The Clovis-sponsored study is designed to assess the safety and activity of the combination in patients with activating EGFR mutation-positive (EGFRm) advanced or metastatic NSCLC.

Rucaparib

During the second quarter of 2016, Clovis intends to complete its rolling NDA submission to the FDA for rucaparib as treatment for advanced ovarian cancer patients with a tumor BRCA mutation (germline and somatic mutations), including platinum-sensitive, -resistant and -refractory patients. In addition, the Company intends to submit an MAA for rucaparib for a comparable ovarian treatment indication by the end of 2016. Enrollment in the ARIEL3 pivotal maintenance study is expected to complete in the next few months, with data expected to be available approximately 12 months later. Pending positive data, supplemental NDAs for maintenance indications in tumor BRCA mutant patients and BRCA-like patients with advanced ovarian cancer are expected to follow.

During the second half of 2016, the Company intends to initiate a study of rucaparib in metastatic castrate-resistant BRCA mutant (inclusive of germline and somatic) prostate cancer patients. In addition, the Company expects to initiate the ARIEL4 confirmatory study in advanced ovarian cancer, including both tumor BRCA mutant and, potentially, BRCA-like patients.

Lucitanib

A Phase 2 program is ongoing to explore lucitanib in patients with treatment-refractory breast cancer. In parallel with Clovis' sponsored study, a Servier-sponsored Phase 2 study of lucitanib in patients with advanced breast cancer is underway to identify the population of patients most likely to benefit from lucitanib therapy.

Conference Call Details

Clovis will hold a conference call to discuss fiscal year 2015 results this afternoon, February 25, 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: **54988734**.

About Rociletinib

Rociletinib is an oral, potent, mutant-selective inhibitor of epidermal growth factor receptor (EGFR) under investigation for the treatment of EGFR-mutated non-small cell lung cancer (NSCLC). Rociletinib targets the activating mutations of EGFR (L858R and Del19), while also inhibiting the dominant acquired resistance mutation, T790M. The T790M mutation develops in approximately 60 percent of patients treated with first- and second-generation EGFR inhibitors. Rociletinib was granted Breakthrough Therapy designation by the U.S. FDA in May 2014. Clovis holds worldwide rights for rociletinib.

About Rucaparib

Rucaparib is an oral, potent small molecule inhibitor of PARP1 and PARP2 being developed for the treatment of ovarian cancer, specifically in 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." Clovis is also exploring rucaparib in other solid tumor types with significant BRCA and BRCA-like populations, including prostate, breast and gastroesophageal cancers. Rucaparib was granted Breakthrough Therapy designation by the U.S. FDA in April 2015. 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, initially targeting advanced breast cancer.

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 December 31,		Twelve Months Ended December 31,	
	2015	**2014**	**2015**	**2014**
Revenues:				
License and milestone revenue	$ -	$ -	$ -	$ 13,625
Operating expenses:				
Research and development	75,995	50,149	269,251	137,705
General and administrative	8,238	5,605	30,524	21,457
Acquired in-process research and development	-	-	12,000	8,806
Impairment of intangible asset	89,557	-	89,557	3,409
Change in fair value of contingent purchase consideration	(26,882)	(1,864)	(24,611)	707
Total expenses	146,908	53,890	376,721	172,084
Operating loss	(146,908)	(53,890)	(376,721)	(158,459)
Other income (expense):				
Interest expense	(2,101)	(2,093)	(8,372)	(2,604)
Foreign currency gains (losses)	736	1,001	2,740	3,580
Other income (expense)	164	(106)	416	(240)
Other income (expense), net	(1,201)	(1,198)	(5,216)	736
Loss before income taxes	(148,109)	(55,088)	(381,937)	(157,723)
Income tax benefit (expense)	28,568	181	29,076	(2,308)
Net loss	$ (119,541)	$ (54,907)	$ (352,861)	$ (160,031)
Basic and diluted net loss per common share	$ (3.12)	$ (1.62)	$ (9.79)	$ (4.72)
Basic and diluted weighted average common shares outstanding	38,321	33,941	36,026	33,889

RECONCILIATION OF GAAP TO NON-GAAP

NET LOSS AND NET LOSS PER SHARE
(in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	**2014**	**2015**	**2014**
GAAP net loss	$ (119,541)	$ (54,907)	$ (352,861)	$ (160,031)
Adjustments:				
Impairment of intangible asset (1)	89,557	-	89,557	-
Change in fair value of contingent purchase consideration (2)	(26,882)	-	(26,882)	-
Income tax benefit (1)	(28,568)	-	(28,568)	-
Non-GAAP net loss	$ (85,434)	$ (54,907)	$ (318,754)	$ (160,031)
GAAP net loss per common share	$ (3.12)	$ (1.62)	$ (9.79)	$ (4.72)
Non-GAAP net loss per common share	$ (2.23)	$ (1.62)	$ (8.85)	$ (4.72)

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 December 31, 2015, the Company recorded an $89.6 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 $28.6 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 December 31, 2015, the Company recorded a $26.9 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 EOS acquisition. 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)

	December 31,	
	2015	2014
Cash and cash equivalents	$278,756	$482,677
Available-for-sale securities	249,832	-
Working capital	464,125	443,400

Total assets	713,386	777,386
Convertible senior notes	279,885	278,680
Common stock and additional paid-in capital	1,130,016	785,123
Total stockholders' equity	300,650	331,630

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