

## Clovis Oncology Announces Third Quarter 2017 Operating Results

November 1, 2017 4:05 PM ET

- *Strong third quarter of launch for Rubraca<sup>®</sup> (rucaparib) in U.S. with \$16.8M reported in net sales*
  - *An additional \$4.4M in commercial value was provided as free drug through our patient assistance program*
- *Submission of a supplemental New Drug Application (sNDA) for rucaparib as maintenance treatment for patients with platinum-sensitive recurrent ovarian cancer completed in early October*
- *Comprehensive ARIEL3 dataset presented at the 2017 European Society for Medical Oncology Congress in Madrid and published in The Lancet demonstrated that rucaparib significantly improved PFS in all ovarian cancer populations studied*
- *Rucaparib E.U. Marketing Authorization Application under review for initial treatment indication; pending this approval Clovis plans to submit a variation to the MAA in early 2018 for maintenance treatment*
- *Broad clinical collaboration with Bristol-Myers Squibb underway to evaluate rucaparib in combination with nivolumab in several late-stage clinical trials in multiple tumor types; studies are expected to begin by YE2017/early 2018*

BOULDER, Colo.--(BUSINESS WIRE)--Nov. 1, 2017-- [Clovis Oncology](#), Inc. (NASDAQ:CLVS) reported financial results for the quarter ended September 30, 2017, and provided an update on the Company's [clinical development programs](#) and regulatory outlook for the remainder of 2017.

“We continue to grow sales quarter over quarter despite our current limited treatment label and the rapid conversion of the ovarian cancer community to favor maintenance therapy with no requirement for diagnostic testing,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “We are obviously very enthusiastic about participating in that broader market based on our ARIEL3 data, which is now under review with the FDA following our submission of a supplemental New Drug Application in October. In addition, we are optimistic about the potential for rucaparib beyond second-line ovarian cancer maintenance, based on our substantial development program which includes front-line ovarian cancer maintenance, a leading effort underway in prostate cancer as well as multiple other tumor types as both monotherapy and in combination with nivolumab.”

### Third Quarter 2017 Financial Results

Clovis reported net product revenue for Rubraca of \$16.8 million for the third quarter of 2017 and \$38.5 million for the first nine months of 2017. During the third quarter, the supply of free drug distributed to eligible patients through our patient assistance plan remained at approximately 20 percent of overall commercial supply. We expect the supply of free drug to remain in this range for the foreseeable future. During the quarter, this represented \$4.4 million in commercial value and \$9.4 million in commercial value for the first nine months of 2017.

Clovis had \$628.0 million in cash, cash equivalents and available-for-sale securities as of September 30, 2017. Cash used in operating activities was \$45.8 million for the third quarter of 2017 and \$195.3 million for the first nine months of 2017, compared with \$60.3 million and \$212.0 million for the comparable periods of 2016. Clovis had approximately 48.9 million shares of common stock outstanding as of September 30, 2017. In January 2017, the Company raised net proceeds of \$221.2 million through an offering of 5.75 million shares of common stock and in June 2017, the Company raised net proceeds of \$324.6 million through an offering of 3.92 million shares of common stock.

Clovis reported a net loss for the third quarter of 2017 of \$60.7 million, or a net loss of \$1.24 per share, and \$294.5 million, or a net loss of \$6.39 per share for the first nine months of 2017. Net loss was \$65.7 million, or a net loss of \$1.70 per share for the third quarter of 2016, and \$278.4 million, or a net loss of \$7.24 per share for the first nine months of 2016. The net loss for the nine months ended September 30, 2017 included a charge of \$117.0 million related to a legal settlement. The net loss for the nine months ended September 30, 2016 included a charge of \$104.5 million for the

impairment of an intangible asset, a gain of \$25.5 million for a reduction in fair value of contingent purchase consideration and a \$29.2 million non-cash tax benefit related to lucitanib product rights recorded in 2013 in connection with the Company's acquisition of Ethical Oncology Science S.p.A. The adjusted net loss excluding these items was \$60.7 million or \$1.24 per share for the third quarter and \$177.5 million or \$3.85 per share for the nine months ended 2017 and \$65.7 million or \$1.70 per share for the third quarter and \$228.5 million or \$5.95 per share for the nine months ended 2016. Net loss for the third quarter of 2017 included share-based compensation expense of \$12.6 million and \$32.2 million for the first nine months of 2017, compared to \$9.2 million and \$29.7 million for the comparable periods of 2016.

Research and development expenses totaled \$38.9 million for the third quarter of 2017 and \$104.5 million for the first nine months of 2017, compared to \$54.3 million and \$196.7 million for the comparable periods in 2016. The decrease year over year is primarily due to lower spending on rucaparib and rociletinib development activities and selling, general and administrative expenses related to the commercialization of Rubraca, which had been classified as research and development prior to FDA approval.

Selling, general and administrative expenses totaled \$35.0 million for the third quarter of 2017 and \$100.4 million for the first nine months of 2017, compared to \$9.2 million and \$28.5 million for the comparable periods in 2016. The increase year over year is primarily due to selling, general and administrative expenses related to the commercialization of Rubraca, which had been classified as research and development prior to FDA approval.

### **Clinical Collaboration with Bristol-Myers Squibb**

In July 2017, Clovis and Bristol-Myers Squibb announced a broad clinical collaboration to evaluate the combination of nivolumab and rucaparib in Phase 2 and pivotal Phase 3 clinical trials in multiple tumor types. The pivotal Phase 3 trials, which will evaluate rucaparib in combination with nivolumab in advanced triple-negative breast cancer and advanced ovarian cancer, are expected to begin in early 2018. The Phase 2 trial will evaluate the safety and efficacy of nivolumab in combination with rucaparib in patients with metastatic castrate-resistant prostate cancer (mCRPC), and is expected to begin by the end of 2017. The planned clinical trials will be conducted in the U.S., Europe and additional countries. Clovis will be the study sponsor and conducting party for the ovarian cancer study and Bristol-Myers Squibb will be the study sponsor and conducting party for the breast and prostate cancer studies. The Clovis-sponsored ovarian cancer study will be known as ATHENA: A Multicenter, Randomized, Double-Blind, Placebo-Controlled study of nivolumab and rucaparib Combination Switch Maintenance Following Front-Line Platinum-based Chemotherapy in Ovarian Cancer Patients.

### **Comprehensive ARIEL3 Dataset Presented at ESMO 2017 and Published in *The Lancet***

The first presentation of the comprehensive dataset from the phase 3 ARIEL3 study of rucaparib took place at the 2017 European Society for Medical Oncology (ESMO) Congress in Madrid in early September, and was subsequently published online in *The Lancet*. The ARIEL3 trial of rucaparib successfully achieved its primary and key secondary endpoints -- improved progression-free survival (PFS) by both investigator review and blinded independent central review (BICR), respectively -- in each of the three populations studied, as well as its exploratory endpoints.

ARIEL3 is a double-blind, placebo-controlled, phase 3 trial of rucaparib that enrolled 564 women with platinum-sensitive, high-grade ovarian, fallopian tube, or primary peritoneal cancer. The primary efficacy analysis evaluated three prospectively defined molecular sub-groups in a step-down manner: 1) tumor BRCA mutant (tBRCAmut) patients, inclusive of germline and somatic mutations of BRCA (n=196); 2) HRD patients, including BRCA-mutant patients and BRCA wild-type with high loss of heterozygosity, or LOH-high patients (n=354), and, finally, 3) the intent-to-treat population, or all patients treated in ARIEL3 (n=564). The study achieved its primary endpoint of improved PFS by investigator review in each of three populations. PFS was also improved in the rucaparib group compared with placebo by BICR, a key secondary endpoint, in all three populations. In addition, rucaparib improved objective response rate vs placebo among evaluable trial participants in all three study populations.

Treatment emergent adverse events (TEAEs) in the ARIEL3 rucaparib group were generally managed with dose modifications and not associated with increased mortality or morbidity compared with the placebo group. Safety data

from ARIEL3 demonstrate consistency with prior rucaparib studies.

In addition, a late-breaker oral presentation describing the ARIEL3 dataset will be presented by Professor Jonathan Ledermann, MD, Professor of Medical Oncology, Director, Cancer Research UK and UCL Cancer Trials Centre, UCL Cancer Institute at the 20th Biennial International Meeting of the European Society for Gynaecological Oncology (ESGO20) on Monday, November 6, 2017, at 8:30 CET in Vienna, Austria.

### **Rucaparib Regulatory Update**

On October 6, Clovis submitted a supplemental New Drug Application (sNDA) to the U.S. Food & Drug Administration (FDA) for rucaparib as maintenance treatment of patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. The sNDA submission is based on data from the Phase 3 ARIEL3 trial.

Clovis' Marketing Authorization Application (MAA) for rucaparib to the European Medicines Agency for an ovarian cancer treatment indication is currently under review. Clovis anticipates an opinion from the Committee for Medicinal Products for Human Use (CHMP) in late 2017, and, if we receive a favorable opinion from CHMP, a potential approval would follow during the first quarter of 2018. Following a potential approval for the treatment indication, Clovis intends to submit a variation to the MAA in Europe for the maintenance treatment indication. Clovis continues to establish its E.U. organization to support a potential launch of rucaparib in 2018.

### **Rucaparib Clinical Development**

Beyond its ovarian cancer development program, the Company is focused on development of multiple tumor types, including prostate cancer. Prostate cancer is the second most diagnosed cancer in men, with 1.1 million new cases diagnosed worldwide in 2012. Men with disease that has advanced to castration-resistant prostate cancer (CRPC) have a high likelihood of having or developing metastases, and metastatic CRPC remains an incurable disease usually associated with poor prognosis and short survival time. Germline and somatic mutations in BRCA, ATM or other homologous recombination (HR) DNA-repair genes are present in patients with advanced prostate cancer (including metastatic CRPC) at frequencies of 20-25 percent and higher. These markers may be used to select metastatic CRPC patients for targeted treatment with rucaparib. Rucaparib has demonstrated cytotoxicity in prostate cancer cells lines with reduced levels of *BRCA1*, *BRCA2*, or *ATM*. In addition, another PARP inhibitor has demonstrated preliminary evidence of anti-tumor activity in mCRPC patients with HRR deficiencies.

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 six months:

- The Clovis-sponsored ARIEL4 confirmatory study in the treatment setting is a Phase 3 multicenter, randomized study of rucaparib versus chemotherapy in relapsed ovarian cancer patients with BRCA mutations who have failed two prior lines of therapy. The primary endpoint of the study is PFS. This study is currently enrolling patients.
- The Clovis-sponsored TRITON2 (Trial of Rucaparib in Prostate Indications) 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 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. This study is currently enrolling patients.
- 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 will compare rucaparib to physician's choice of AR-targeted therapy or chemotherapy in these patients. This study is currently enrolling patients.
- The Clovis-sponsored ATHENA (A Multicenter, Randomized, Double-Blind, Placebo-Controlled study of

nivolumab and rucaparib Combination Switch Maintenance Following Front-Line Platinum-based Chemotherapy in Ovarian Cancer Patients) study in advanced ovarian cancer in the first-line maintenance treatment setting evaluating rucaparib plus nivolumab (anti-PD1), rucaparib, nivolumab 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 Spring 2018.

- A Clovis-sponsored Phase 2 open-label monotherapy study of rucaparib in recurrent, metastatic bladder cancer titled ATLAS: A Study of Rucaparib in Patients with Locally Advanced or Metastatic Urothelial Carcinoma. This study is expected to initiate in Spring 2018.
- The Phase 3 pivotal study in advanced triple-negative breast cancer (TNBC) to evaluate nivolumab and rucaparib in combination. This study is sponsored by Bristol-Myers Squibb and is expected to begin in Spring 2018.
- The Phase 2 combination study of nivolumab in combination with rucaparib for the treatment of mCRPC. This study, sponsored by Bristol-Myers Squibb, will be conducted as an arm of a larger Bristol-Myers Squibb-sponsored prostate cancer study. This study is expected to begin before the end of 2017.
- The Phase 1b combination study of the cancer immunotherapy Tecentriq (atezolizumab; anti-PDL1) and rucaparib for the treatment of gynecological cancers, with a focus on ovarian cancer. This study is sponsored by Roche and is currently enrolling patients.

Exploratory studies in other tumor types are also underway.

### Conference Call Details

Clovis will hold a conference call to discuss third quarter 2017 results on November 1 at 4:30pm ET. The conference call will be simultaneously webcast on the Company's web site at [www.clovisoncology.com](http://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: **7792319**.

### About Rubraca® (rucaparib)

Rubraca is a PARP inhibitor indicated in the U.S. as monotherapy for the treatment of patients with deleterious *BRCA* mutation (germline and/or somatic) associated advanced ovarian cancer, who have been treated with two or more chemotherapies, and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. The indication for Rubraca is approved under the FDA's accelerated approval program based on objective response rate and duration of response, and is based on results from two multicenter, single-arm, open-label clinical trials. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Please visit [rubraca.com](http://rubraca.com) for more information.

### About Rucaparib

Rucaparib is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in ovarian cancer as well as several additional solid tumor indications. During the fourth quarter of 2016, the Marketing Authorization Application (MAA) submission in Europe for rucaparib in an ovarian cancer treatment indication was submitted and accepted for review. In October 2017, Clovis Oncology submitted a supplemental New Drug Application (sNDA) in the U.S. for a second line or later maintenance treatment indication in ovarian cancer based on the ARIEL3 data, and in early 2018, plans to file a variation of the MAA in Europe for the maintenance treatment indication upon receipt of a potential approval for the treatment indication. Studies open for enrollment or under consideration include ovarian, prostate, breast, gastroesophageal, pancreatic, lung, bladder and urothelial 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, 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](http://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 sNDA and submission, review and approval of the MAA for rucaparib. 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 clinical development programs for our drug candidates, including the result of clinical trials, whether future study results will be consistent with study findings to-date, the corresponding development pathways of our companion diagnostics, the timing of availability of data from our clinical trials and the results of our clinical trials, 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 that may affect drug labeling, pricing and reimbursement, and other matters that could affect the 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)

	<b>Three Months Ended</b>		<b>Nine Months Ended September</b>	
	<b>September 30,</b>		<b>30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Revenues:				
Product revenue, net	\$ 16,806	\$ -	\$ 38,471	\$ -
Operating expenses:				
Cost of sales - product	3,026	-	6,920	-
Cost of sales - intangible asset amortization	372	-	1,115	-
Research and development	38,924	54,338	104,479	196,675
Selling, general and administrative	35,011	9,162	100,384	28,541
Acquired in-process research and development	-	500	-	800
Impairment of intangible asset	-	-	-	104,517
Change in fair value of contingent purchase consideration	-	-	-	(24,936 )
Total expenses	77,333	64,000	212,898	305,597
Operating loss	(60,527 )	(64,000 )	(174,427 )	(305,597 )
Other income (expense):				
Interest expense	(2,618 )	(2,108 )	(7,796 )	(6,318 )

Foreign currency loss	(44 )	(66 )	(127 )	(434 )
Legal settlement loss, net of insurance receivable	-	-	(117,000 )	-
Other income	1,291	252	2,237	473
Other expense, net	(1,371 )	(1,922 )	(122,686 )	(6,279 )
Loss before income taxes	(61,898 )	(65,922 )	(297,113 )	(311,876 )
Income tax benefit	1,234	227	2,599	33,467
Net loss	\$ (60,664 )	\$ (65,695 )	\$ (294,514 )	\$ (278,409 )
Basic and diluted net loss per common share	\$ (1.24 )	\$ (1.70 )	\$ (6.39 )	\$ (7.24 )
Basic and diluted weighted-average common shares outstanding	48,917	38,538	46,062	38,429

### RECONCILIATION OF GAAP TO NON-GAAP NET LOSS AND NET LOSS PER SHARE

(Unaudited, in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
GAAP net loss	\$ (60,664 )	\$ (65,695 )	\$ (294,514 )	\$ (278,409 )
Adjustments:				
Legal settlement loss (1)	-	-	117,000	-
Impairment of intangible asset (2)	-	-	-	104,517
Change in fair value of contingent purchase consideration (3)	-	-	-	(25,452 )
Income tax benefit (2)	-	-	-	(29,160 )
Non-GAAP net loss	\$ (60,664 )	\$ (65,695 )	\$ (177,514 )	\$ (228,504 )
GAAP net loss per common share	\$ (1.24 )	\$ (1.70 )	\$ (6.39 )	\$ (7.24 )
Non-GAAP net loss per common share	\$ (1.24 )	\$ (1.70 )	\$ (3.85 )	\$ (5.95 )

*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, 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.

(2) 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.

(3) 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

(Unaudited, in thousands)

	September 30, 2017	December 31, 2016
Cash and cash equivalents	\$ 611,472	\$ 216,186
Available-for-sale securities	16,499	49,997
Working capital	479,513	193,751
Total assets	805,359	364,557
Convertible senior notes	282,082	281,126
Common stock and additional paid-in capital	1,767,446	1,174,989
Total stockholders' equity (deficit)	299,189	(3,634 )

### Other Data

(Unaudited, in thousands)

	Nine Months Ended September 30,	
	2017	2016
Net cash used in operating activities	(195,326 )	\$ (212,005 )
Share Based Compensation Expense	32,201	\$ 29,744

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Source: Clovis Oncology, Inc.

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