**Clovis Oncology Announces 2017 Operating Results**

February 26, 2018 4:06 PM ET

- *First full year of Rubraca® (rucaparib) U.S. sales totaled $55.5M, including $17.0M for the fourth quarter of 2017, with limited third-line BRCA-mutant ovarian cancer treatment label*
- *U.S. maintenance treatment indication under review, with April 6, 2018 PDUFA date*
- *CHMP positive trend vote communicated for limited treatment indication; formal CHMP vote anticipated in March 2018*
- *Maintenance variation to MAA planned following potential Q2 approval for treatment indication*
- *Robust Clovis-sponsored Rubraca development program in place; clinical studies in ovarian, prostate and bladder cancers open for enrollment or initiating 1H2018*
- *Broad clinical collaboration with Bristol-Myers Squibb underway to evaluate Rubraca in combination with Opdivo® (nivolumab) in several late-stage clinical trials in multiple tumor types; prostate study underway, ovarian and breast cancer studies expected to begin 1H2018*
- *$563.7M in cash, cash equivalents and available for sale securities at December 31, 2017*

BOULDER, Colo.--(BUSINESS WIRE)--Feb. 26, 2018-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for the quarter and year ended December 31, 2017, and provided an update on the Company's clinical development programs and regulatory and commercial outlook for 2018.

"2017 provided us strong momentum for 2018, with a potential all-comers maintenance approval in the U.S. coming soon, and a potential positive recommendation in Europe by year-end for Rubraca also in the all-comers ovarian cancer maintenance population," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "In addition, we have initiated or plan to shortly initiate a broad clinical development program for Rubraca both as monotherapy and in combination with Bristol-Myers Squibb's Opdivo in multiple tumor types including ovarian, prostate, triple-negative breast and bladder cancers. We believe that Rubraca as monotherapy or in combination with Opdivo has the potential to be foundational in the treatment of multiple tumor types and we are fully committed to exploring this potential."

**Fourth Quarter and Year-End 2017 Financial Results**

Clovis reported net product revenue for Rubraca of $17.0 million for the fourth quarter of 2017 and $55.5 million for the year ended December 31, 2017. During the fourth quarter, the supply of free drug distributed to eligible patients through the Rubraca patient assistance program 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. This represented $4.7 million in commercial value for the fourth quarter and $14.1 million in commercial value for the full year. Net product revenue for the quarter and full year ended December 31, 2016 was $78 thousand, following the initial approval and launch of Rubraca in the treatment setting on December 19, 2016.

Clovis had $563.7 million in cash, cash equivalents and available-for-sale securities as of December 31, 2017. Cash used in operating activities was $65.6 million for the fourth quarter of 2017 and $260.9 million for the year ended December 31, 2017, compared with $54.7 million and $266.7 million for the comparable periods of 2016. This includes product supply costs of $12.0 million in the fourth quarter of 2017 and $53.5 million for the year ended December 31, 2017, compared to zero and $19.2 million for the comparable periods in 2016. Clovis had approximately 50.6 million shares of common stock outstanding as of December 31, 2017. In January 2017, Clovis raised net proceeds of $221.2 million through an offering of 5.75 million shares of common stock and in June 2017, Clovis 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 fourth quarter of 2017 of $51.9 million, or ($1.04) per share, and $346.4 million or ($7.36) per share for the year ended December 31, 2017. The net loss for the fourth quarter of 2016 was $70.7 million, or ($1.83) per share and $349.1 million, or ($9.07) per share for the year ended December 31, 2016. Net loss for the fourth

quarter of 2017 included share-based compensation expense of $12.5 million and $44.7 million for the full year 2017, respectively, compared to $10.1 million and $39.8 million for the comparable periods of 2016.

The net loss for the year ended December 31, 2017 included a charge of $105.5 million related to the portion of a legal settlement that was paid in Clovis common stock. The net loss for the year ended December 31, 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. The adjusted net loss excluding these items was $63.4 million or ($1.27) per share for the fourth quarter and $240.9 million or ($5.12) per share for the full year ended 2017 and $70.7 million or ($1.83) per share for the fourth quarter and $299.2 million or ($7.78) per share for the full year 2016.

Research and development expenses totaled $38.0 million for the fourth quarter of 2017, and $142.5 million for the full year 2017, compared to $54.5 million and $251.1 million, respectively, for the comparable periods in 2016. The decrease year over year is primarily due to lower spending on Rubraca 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 $38.5 million for the fourth quarter of 2017, and $138.9 million for the full year 2017, compared to $12.2 million and $40.7 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.

**Key Milestones and Objectives for Rubraca**

**U.S. sNDA for Ovarian Cancer Maintenance Treatment Indication based on ARIEL3 Dataset**

In December 2017, the U.S. Food and Drug Administration (FDA) accepted the Company’s supplemental New Drug Application (sNDA) for Rubraca for a second line or later maintenance treatment indication in ovarian cancer based on the ARIEL3 data. The FDA granted priority review status to the application with a Prescription Drug User Fee Act (PDUFA) date of April 6, 2018.

The first presentation of the comprehensive dataset from the Phase 3 ARIEL3 study of Rubraca took place at the 2017 European Society for Medical Oncology (ESMO) Congress in Madrid in early September, and was subsequently published in *The Lancet*. The ARIEL3 trial of Rubraca 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.

ARIEL3 is a double-blind, placebo-controlled, Phase 3 trial of Rubraca 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 (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 Rubraca group compared with placebo by BICR, a key secondary endpoint, in all three populations. In addition, Rubraca improved objective response rate vs placebo among evaluable trial participants in all three study populations.

Treatment emergent adverse events (TEAEs) in the ARIEL3 Rubraca 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 Rubraca studies.

**European Union (EU) Regulatory Update**

Last week Clovis announced that the Committee for Medicinal Products for Human Use (CHMP) has communicated a

positive trend vote for the Marketing Authorization Application (MAA) for rucaparib under review for the treatment of a limited population of women with advanced BRCA-mutant ovarian cancer and expects to vote on the treatment indication at their scheduled meeting in March 2018. The indication under consideration by the CHMP focuses on a subset of platinum-sensitive disease where there is particular unmet medical need. Pending a positive recommendation by CHMP, final approval by the European Commission would follow in Q2 2018, and Clovis plans to submit a variation to the Marketing Authorization for the maintenance treatment indication, with the CHMP recommendation anticipated by the end of 2018. Clovis continues to establish its EU organization to support a potential launch of Rubraca in 2018.

**Clinical Collaboration with Bristol-Myers Squibb**

In July 2017, Clovis and Bristol-Myers Squibb announced a broad clinical collaboration to evaluate the combination of Opdivo and Rubraca in Phase 2 and pivotal Phase 3 clinical trials in multiple tumor types. The pivotal Phase 3 trials, which will evaluate Rubraca in combination with Opdivo in advanced triple-negative breast cancer and advanced ovarian cancer, are expected to begin in the first half of 2018. The Phase 2 trial will evaluate the safety and efficacy of Opdivo in combination with Rubraca in patients with metastatic castrate-resistant prostate cancer (mCRPC), and initiated in December 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.

**Initiation of TRITON Prostate Clinical Development Program**

Beyond its ovarian cancer development program, the Company is focused on development of Rubraca in 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 Rubraca. 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 HR deficiencies.

In February 2017, Clovis and Strata Oncology announced an agreement to accelerate patient identification and enrollment for the ongoing TRITON prostate cancer development program. The Strata trial, sponsored by Strata, is an observational study that provides next-generation sequencing at no cost to all advanced cancer patients at participating clinical sites, and match advanced prostate cancer patients with specified mutations to Clovis' TRITON studies for Rubraca. Strata has agreed not to provide similar matching services on behalf of any other collaborator for any other mCRPC clinical trial for patients having the same specified mutations.

**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 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 a medical meeting in Fall 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 will compare Rubraca to physician's choice of AR-targeted therapy or chemotherapy in these patients. This study is currently enrolling patients.
- The Clovis-sponsored ATHENA study in advanced ovarian cancer in the first-line maintenance treatment setting evaluating Rubraca plus Opdivo (anti-PD1), 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.
- 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 open for enrollment.
- 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 and is expected to begin in the first half of 2018.
- 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.
- The Phase 1 RUCA-J study, sponsored by Clovis, initiated last week 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.

Exploratory studies in other tumor types are also underway.

**Conference Call Details**

Clovis will hold a conference call to discuss Q4/FY 2017 results this afternoon, February 26, at 4:30 pm 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: **3097118.**

**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 on an accelerated basis 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. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. In December 2017, the U.S. Food and Drug Administration (FDA) accepted the Company's supplemental New Drug Application (sNDA) for Rubraca for a second-line or later maintenance treatment indication in ovarian cancer based on the ARIEL3 data. The FDA granted Priority Review status to the application with a Prescription Drug User Fee Act (PDUFA) date of April 6, 2018.

In February 2018, the CHMP communicated a positive trend vote for the rucaparib MAA under review for an ovarian cancer treatment indication and expects to vote on the indication at their March 2018 meeting. Rucaparib is an unlicensed medical product in the EU.

## 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 sNDA for the maintenance treatment indication and 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 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 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 December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | **2017** | **2016** | **2017** | **2016** |
| Revenues: | | | | |
| Product revenue, net | $ 17,040 | $ 78 | $ 55,511 | $ 78 |
| | | | | |
| Operating expenses: | | | | |
| Cost of sales - product | 3,332 | 70 | 10,251 | 70 |
| Cost of sales - intangible asset amortization | 370 | - | 1,486 | - |
| Research and development | 38,019 | 54,454 | 142,498 | 251,129 |

| | | | | |
|---|---|---|---|---|
| Selling, general and administrative | 38,523 | 12,190 | 138,907 | 40,731 |
| Acquired in-process research and development | - | 500 | - | 1,300 |
| Impairment of intangible asset | - | - | - | 104,517 |
| Change in fair value of contingent purchase consideration | - | - | - | (24,936) |
| Total expenses | 80,244 | 67,214 | 293,142 | 372,811 |
| Operating loss | (63,204) | (67,136) | (237,631) | (372,733) |
| Other income (expense): | | | | |
| Interest expense | (2,631) | (2,173) | (10,428) | (8,491) |
| Foreign currency gain (loss) | 45 | (146) | (82) | (580) |
| Legal settlement loss | 11,523 | - | (105,477) | - |
| Other income (expense) | 1,404 | 160 | 3,643 | 633 |
| Other income (expense), net | 10,341 | (2,159) | (112,344) | (8,438) |
| Loss before income taxes | (52,863) | (69,295) | (349,975) | (381,171) |
| Income tax benefit | 980 | (1,433) | 3,578 | 32,034 |
| Net loss | $ (51,883) | $ (70,728) | $ (346,397) | $ (349,137) |
| Basic and diluted net loss per common share | $ (1.04) | $ (1.83) | $ (7.36) | $ (9.07) |
| Basic and diluted weighted-average common shares outstanding | 49,973 | 38,624 | 47,047 | 38,478 |

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

| | **Three Months Ended December 31,** | | **Twelve Months Ended December 31,** | |
|---|---|---|---|---|
| | **2017** | **2016** | **2017** | **2016** |
| GAAP net loss | $ (51,883) | $ (70,728) | $ (346,397) | $ (349,137) |
| Adjustments: | | | | |
| Legal settlement loss (1) | (11,523) | - | 105,477 | - |
| 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 | $ (63,406) | $ (70,728) | $ (240,920) | $ (299,232) |
| GAAP net loss per common share | $ (1.04) | $ (1.83) | $ (7.36) | $ (9.07) |

| | | | | |
|---|---|---|---|---|
| Non-GAAP net loss per common share | $ (1.27) | $ (1.83) | $ (5.12) | $ (7.78) |

*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 twelve months ended December 31, 2017, the Company recorded a $105.5 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. During the three months ended December 31, 2017, the Company recorded an $11.5 million decrease to the legal settlement loss due to the difference in the volume weighted average price of the Company's stock over the 10 trading days immediately preceding the October 26, 2017 hearing date and the closing stock price on November 2, 2017, the date the Company issued the shares related to the legal settlement.

(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)

| | **December 31, 2017** | **December 31, 2016** |
|---|---|---|
| Cash and cash equivalents | $ 464,198 | $ 216,186 |
| Available-for-sale securities | 99,533 | 49,997 |
| Working capital | 545,424 | 213,813 |
| Total assets | 735,230 | 364,557 |
| Convertible senior notes | 282,406 | 281,126 |
| Common stock and additional paid-in capital | 1,887,249 | 1,174,989 |
| Total stockholders' equity (deficit) | 367,636 | (3,634) |

**Other Data**
(Unaudited, in thousands)

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | **2017** | **2016** | **2017** | **2016** |
| Net cash used in operating activities | (65,578) | $ (54,675) | (260,904) | $ (266,680) |
| Share Based Compensation Expense | 12,506 | $ 10,052 | 44,707 | $ 39,796 |

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Source: Clovis Oncology, Inc.

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