



NEWS RELEASE

Clovis Oncology Announces Second Quarter 2020 Operating Results

8/6/2020

- \$39.9M in Rubraca® (rucaparib) global sales for Q2 2020 and \$82.5M for H1 2020; net product revenue up 21% over Q2 2019 and 25% over H1 2019
- \$261.4M in cash and cash equivalents at June 30, 2020; anticipated to fund operating plan into early 2022
- Rubraca approved in the U.S. as monotherapy treatment for patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer (mCRPC) on May 15; virtual U.S. launch in mCRPC underway
- Completed target enrollment in the Phase 3 ATHENA trial evaluating Rubraca with and without Opdivo ® in front-line, newly-diagnosed advanced ovarian cancer
- Phase 2 portion of LIO-1 combination study of lucitanib and Opdivo in gynecologic cancers now enrolling
- Investigational New Drug (IND) applications for FAP-2286 as both imaging and treatment agent planned in Q4 2020
- Data for all three of Clovis Oncology commercial or development-stage products to be presented at the 2020 ESMO Virtual Congress in September

BOULDER, Colo.--(BUSINESS WIRE)-- **Clovis Oncology**, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended June 30, 2020, and provided an update on the Company's **clinical development programs** and regulatory and commercial outlook for the rest of the year.

"We are pleased with our U.S. approval in advanced prostate cancer and continued sales growth for Rubraca year over year in the U.S. and Europe, particularly in the face of evident headwinds from COVID-19. Second-quarter revenues were negatively affected, largely due to fewer new patient starts, as oncology practices and patients adjusted to the impact of the virus in the U.S. and Europe," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We continue to believe that Rubraca has significant advantages as a maintenance option in ovarian cancer and a treatment option for prostate cancer in an environment in which physicians are trying to reduce patient visits to their clinics, and will continue our efforts to engage with clinicians during this period, which is ongoing as resurgences of the virus continue in large U.S. markets. I am pleased that we successfully completed

target enrollment in the 1000 patient Phase 3 ATHENA study in front-line, newly diagnosed advanced ovarian cancer maintenance in June in less than two years. We are also particularly enthusiastic to be moving FAP-2286 into the clinic with planned imaging and therapeutic INDs in the fourth quarter.”

Second Quarter 2020 Financial Results

Clovis reported net product revenue for Rubraca of \$39.9 million for the second quarter of 2020, which included U.S. product revenue of \$36.7 million and ex-U.S. product revenue of \$3.2 million, compared to net product revenue for Q2 2019 of \$33.0 million, which included U.S. net product revenue of \$32.7 million and ex-U.S. net product revenue of \$0.3 million. U.S. product revenues increased 12 percent in Q2 2020 compared to Q2 2019 and ex-U.S. product revenue increased meaningfully from the first reported ex-U.S. sales in Q2 2019.

Clovis reported net product revenue for Rubraca of \$82.5 million for the six months ended June 30, 2020, which included U.S. product revenue of \$76.0 million and ex-U.S. product revenue of \$6.5 million, compared to net product revenue for same period in 2019 of \$66.1 million, which included U.S. net product revenue of \$64.6 million and ex-U.S. net product revenue of \$1.5 million.

Net product revenue decreased six percent sequentially from Q1 2020 to Q2 2020 principally due to reduced new patient starts which we believe is the result of the effects of COVID-19 in the U.S. and Europe during the quarter. The effects of COVID-19 on future sales are difficult to predict, especially with the increase in COVID-19 cases in the U.S. and Europe.

Clovis had \$261.4 million in cash and cash equivalents as of June 30, 2020, including \$82.8 million in net proceeds in an equity offering of 11.1 million shares of common stock in May 2020.

The Company has reduced its total outstanding convertible debt by \$145.1 million in outstanding principal amount from December 31, 2019 through June 30, 2020.

As of June 30, 2020, the Company had drawn approximately \$68 million under the TPG ATHENA clinical trial financing and had up to \$107 million available to draw under the agreement to fund the expenses of the ATHENA trial through Q3 2022.

Based on the Company's anticipated revenues, spending, available financing sources and existing cash and cash equivalents, the Company believes it has sufficient cash and cash equivalents to fund its operating plan into early 2022, after taking into account any cash repayment (unless refinanced earlier) of the remaining \$64.42 million aggregate principal amount of the 2.50% convertible notes, at their maturity in September 2021.

Net cash used in operating activities was significantly lower at \$59.9 million for the second quarter of 2020, compared with \$98.0 million for the second quarter of 2019. Similarly, net cash used in operating activities for the first half of 2020 was \$142.4 million, compared with \$196.5 million for the first half of 2019.

Borrowings under the TPG ATHENA financing provided \$17.7 million in cash in Q2 2020, and we paid a milestone payment to Pfizer of \$8.0 million for the U.S. mCRPC approval. Cash burn in Q2 2020 was \$50.1 million, which represents a 25 percent decline from the Q1 2020 cash burn of \$66.9 million. Cash burn in the first half of 2020 was \$117.0 million.

Clovis reported a net loss for the second quarter of 2020 of \$92.2 million, or (\$1.15) per share, and a net loss of \$191.6 million, or (\$2.52) per share, for the first half of 2020. Net loss for Q2 2019 was \$120.4 million, or (\$2.27) per share, and \$206.9 million, or a net loss of (\$3.91) per share, for the first half of 2019. Net loss for Q2 and the first half of 2020 included share-based compensation expense of \$13.3 million and \$26.3 million, compared to \$14.1 million and \$27.8 million for the comparable periods of 2019.

Research and development expenses totaled \$69.9 million for Q2 2020 and \$138.1 million for the first half of 2020, compared to \$70.7 million and \$132.8 million for the comparable periods in 2019. Research and development expenses remained relatively flat for the second quarter and increased slightly for the first half of 2020 compared to the same period in the prior year. We expect research and development expenses to be lower in the full year 2021 compared to full year 2020.

Selling, general and administrative expenses totaled \$41.9 million for Q2 2020 and \$84.5 million for the first half of 2020, compared to \$48.0 million and \$95.8 million for the comparable periods in 2019. Selling, general and administrative expenses decreased during the second quarter and first half of 2020 compared to the same period in the prior year with savings due to the COVID-19 situation globally and overall cost reduction efforts.

U.S. Approval and Label Expansion for Rubraca now includes BRCA1/2-mutant mCRPC

On May 15, 2020, the U.S. FDA approved Rubraca for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castrate-resistant prostate cancer who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. The FDA approved this indication under accelerated approval based on objective response rate and duration of response data from the multi-center, single arm TRITON2 clinical trial.

In late May, the National Comprehensive Cancer Network® (NCCN) updated its Clinical Practice Guidelines in Oncology for Prostate Cancer to include new recommendations for Rubraca. In addition to its ovarian cancer recommendations, Rubraca is now recommended in the NCCN Guidelines® for the treatment of patients with

BRCA-mutant tumors with mCRPC under second-line treatment and subsequent therapy as a Category 2A recommendation inclusive of the following:

Rucaparib is a treatment option for patients with mCRPC and a pathogenic BRCA1 or BRCA2 mutation (germline and/or somatic) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. If the patient is not fit for chemotherapy, rucaparib can be considered even if taxane-based therapy has not been given.

Target Enrollment Completed in the Phase 3 ATHENA Study

In June, the Company announced the completion of target enrollment of 1000 patients in the Clovis-sponsored Phase 3 ATHENA trial evaluating Rubraca as monotherapy and the combination of Rubraca and Opdivo as front-line maintenance treatment of newly-diagnosed advanced ovarian cancer. ATHENA is the first front-line switch maintenance study designed to evaluate PARP monotherapy and PARP/PD-1 combination therapy in one study design. Target enrollment of 1000 patients in the ATHENA study was achieved in less than two years with the support and involvement of the Gynecologic Oncology Group (GOG) and the European Network for Gynecological Oncological Trials (ENGOT), two of the largest cooperative groups in the U.S. and Europe dedicated to the treatment of gynecological cancers.

In addition, three abstracts describing data from rucaparib monotherapy or combination clinical trials were accepted for e-poster presentation at the 2020 ESMO Virtual Congress in September.

Lucitanib Combination Studies Underway

Two Clovis-sponsored early Phase 1b/2 lucitanib combination studies are currently underway: LIO-1, evaluating lucitanib and Opdivo in combination in advanced solid tumors (Phase 1b) and gynecologic cancers (Phase 2); and lucitanib in combination with rucaparib in advanced solid tumors (Phase 1b) and ovarian cancer (Phase 2) as an arm of the SEASTAR study. An abstract describing the initial Phase 1b clinical experience of lucitanib in combination with Opdivo (LIO-1) has been accepted as an e-poster for the 2020 European Society of Medical Oncology (ESMO) Virtual Congress to be held in September. In addition, the Phase 2 portion of LIO-1 recently opened for enrollment and treated the first patient in the trial, and a Trials-In-Progress e-poster describing the trial design was also accepted for the 2020 ESMO Virtual Congress.

FAP-2286 and Peptide-Targeted Radiotherapy Development Program

The Company's peptide-targeted radiopharmaceutical therapy development program includes lead compound FAP-2286 and three additional unnamed preclinical targets. An abstract describing the first presentation of FAP-2286

preclinical data in animal models has been accepted for the 2020 ESMO Virtual Congress, and during Q4 2020, Clovis intends to submit two Investigational New Drug (IND) applications for FAP-2286 for use as imaging and treatment agents respectively. Upon activation of the INDs by the U.S. FDA, Clovis will initiate a Phase 1 study to determine the dose and tolerability of the FAP-targeting therapeutic agent, with expansion cohorts planned in multiple tumor types. The FAP-targeting imaging agent will be utilized to identify tumors that contain FAP for treatment in the Phase 1 study.

Conference Call Details

Clovis will hold a conference call to discuss Q2 2020 results this afternoon, August 6, at 4:30pm ET. The conference call will be simultaneously webcast on the Clovis Oncology web site www.clovisoncology.com, and archived for future review. Dial-in numbers for the conference call are as follows: US participants (877) 698-7048, International participants (647) 689-5448, conference ID: 7155799.

About Rubraca (rucaparib)

Rubraca is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed multiple tumor types, including ovarian and prostate cancers, as monotherapy and in combination with other anti-cancer agents. Exploratory studies in other tumor types are also underway. Clovis holds worldwide rights for Rubraca.

In the United States, Rubraca is approved for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Rubraca is also approved in the United States for the treatment of adult patients with deleterious BRCA mutation (germline and/or somatic) associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. Additionally, Rubraca is approved in the U.S. for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Patients should be selected for treatment with Rubraca based on the presence of a deleterious BRCA mutation (germline and/or somatic). This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The TRITON3 clinical trial is expected to serve as the confirmatory study for the Rubraca accelerated approval in mCRPC.

In Europe, Rubraca is approved for the maintenance treatment of adults with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. Rubraca is also approved in Europe for the treatment of adult patients with

platinum sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum-based chemotherapy, and who are unable to tolerate further platinum-based chemotherapy.

Rubraca is an unlicensed medical product outside of the U.S. and Europe.

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 (PDGFR α / β) and fibroblast growth factor receptors 1 through 3 (FGFR1-3). Emerging clinical data support the combination of angiogenesis inhibitors and immunotherapy to increase effectiveness in multiple cancer indications. Angiogenic factors, such as vascular endothelial growth factor (VEGF), are frequently up-regulated in tumors and create an immunosuppressive tumor microenvironment. Use of antiangiogenic drugs may reverse this immunosuppression and augment response to immunotherapy.

Lucitanib is an unlicensed medical product.

About FAP-2286

FAP-2286 is a preclinical candidate discovered by 3B Pharmaceuticals under investigation as a peptide-targeted radionuclide therapy (PRT) and imaging agent targeting fibroblast activation protein alpha (FAP). FAP is highly expressed in many epithelial cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas. Clovis is planning to submit an investigational new drug application (IND) for FAP-2286 in the second half of 2020. Clovis will conduct the global clinical trials and holds U.S. and global rights, excluding Europe.

FAP-2286 is an unlicensed medical product.

About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical second 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, for those indications that require them, 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, with additional office locations in the U.S. and Europe. Please visit www.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. Examples of forward-looking statements contained in this press release include, among others, statements regarding our future financial and operating performance, business plans or prospects, including expectations concerning our future cash position, our expectations regarding the impact of COVID-19 on our business operations and results, including future revenues, supply and distribution of our clinical trial supplies and commercial product supplies, our expectations regarding our ability to maintain the enrollment and conduct of our clinical trials and other development activities, expectations concerning future regulatory activities, our plans for commercial launch in expanded indications in the United States, our plans for commercial launch in additional countries, expectations for submission of regulatory filings, our plans to present final or interim data on ongoing clinical trials, our plans to submit additional data to, or meet with, the FDA with respect to the status of or plans for ongoing or planned trials, the timing and pace of commencement of enrollment in and conduct of our clinical trials and the cost of certain trials, including those being considered, planned or conducted in collaboration with partners, our plans for commencement of additional planned trials, the potential results of such clinical trials, changes in drug supply timing and costs and other expenses and statements regarding our expectations of the supply of free drug distributed to eligible patients and our expectations regarding the funding that may be available to us under the agreement with TPG Sixth Street Partners. 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 impacts of the COVID-19 pandemic and disruption related to efforts to mitigate its spread on our business, results of operations or financial condition, including impacts on the vendors or distribution channels in our supply chain, impacts on our contract manufacturers' ability to continue to manufacture our products, impacts on our ability to continue our development activities, impacts on the conduct of our clinical trials, including with respect to enrollment rates, availability of investigators and clinical trial sites or monitoring of data and impact on the ability and timing of our field personnel to conduct their activities with health care providers, the uncertainties inherent in the effect our future revenues or expenses may have on our cash position, the market potential of our approved drug, including the performance of our sales and marketing efforts and the success of competing drugs and therapeutic approaches, changes in gross-to-net or free drug provided through our patient assistance program, the availability of reimbursement and insurance coverage, the performance of our third-party manufacturers, whether our clinical development programs for our drug candidates and those of our partners can be completed on time or at all, whether future study results will be consistent with study findings to date and whether future study results will support continued development or regulatory approval, the corresponding development pathways of our companion diagnostics, the timing of availability of data from our clinical trials and the results, the initiation, enrollment, timing and results of our planned clinical trials, the risk that final results of ongoing trials may differ from initial or interim results as a result of factors such as final results from a larger patient population may be different from initial or interim results from a smaller patient population, actions by the FDA, the EMA or other

regulatory authorities regarding data required to support drug applications and whether to accept or approve drug applications that may be filed, their interpretations of our data and agreement with our regulatory approval strategies or components of our filings, including our clinical trial designs, conduct and methodologies, as well as their decisions regarding drug labeling, reimbursement and pricing, and other matters that could affect the development, approval, 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Product revenue	\$ 39,887	\$ 32,978	\$ 82,451	\$ 66,096
Operating expenses:				
Cost of sales - product	9,120	6,445	18,216	13,851
Cost of sales - intangible asset amortization	1,280	1,217	2,492	2,337
Research and development	69,878	70,746	138,099	132,777
Selling, general and administrative	41,902	48,029	84,500	95,791
Other operating expenses	355	-	3,805	-
Total expenses	<u>122,535</u>	<u>126,437</u>	<u>247,112</u>	<u>244,756</u>
Operating loss	(82,648)	(93,459)	(164,661)	(178,660)
Other income (expense):				
Interest expense	(6,739)	(3,817)	(16,300)	(7,407)
Foreign currency loss	142	(226)	(735)	(419)
Loss on convertible notes conversion	-	-	(7,791)	-
Loss on extinguishment of debt	(3,277)	-	(3,277)	-
Legal settlement loss	-	(25,000)	-	(25,000)
Other income	239	1,899	1,081	4,300
Other income (expense), net	<u>(9,635)</u>	<u>(27,144)</u>	<u>(27,022)</u>	<u>(28,526)</u>
Loss before income taxes	(92,283)	(120,603)	(191,683)	(207,186)
Income tax benefit	36	176	104	336
Net loss	<u>\$ (92,247)</u>	<u>\$ (120,427)</u>	<u>\$ (191,579)</u>	<u>\$ (206,850)</u>
Basic and diluted net loss per common share	\$ (1.15)	\$ (2.27)	\$ (2.52)	\$ (3.91)
Basic and diluted weighted-average common shares	80,453	53,028	76,057	52,960

CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

	June 30, 2020	Dec 31, 2019
Cash and cash equivalents	\$ 261,436	\$ 161,833
Available-for-sale securities	-	134,826
Working capital	210,254	233,384
Total assets	628,209	669,604
Convertible senior notes	504,680	644,751
Common stock and additional paid-in capital	2,382,632	2,114,123
Total stockholders' deficit	(97,375)	(174,257)

Other Data
(Unaudited, in thousands)

	Six Months Ended June 30,	2020	2019

Net cash used in operating activities	(142,351)	(196,488)
Share Based Compensation Expense	26,274	27,769

RECONCILIATION OF NET CASH USED IN OPERATING
ACTIVITIES TO CASH BURN
(Unaudited, in thousands)

	Three Months Ended June 30, 2020	Six Months Ended June 30, 2020
Net cash used in operating activities	\$ (59,857)	\$ (142,351)
Adjustments:		
Acquired in-process research and development - milestone payment	(8,000)	(8,000)
Proceeds from borrowings under financing agreement	17,730	33,322
Cash burn	<u>\$ (50,127)</u>	<u>\$ (117,029)</u>
Net cash provided by investing activities	\$ 56,800	\$ 126,607
Net cash provided by financing activities	\$ 101,007	\$ 115,651

To supplement our financial statements prepared in accordance with U.S. GAAP, we monitor and consider cash burn, which is a non-U.S. GAAP financial measure. This non-U.S. GAAP financial measure is not based on any standardized methodology prescribed by U.S. GAAP and is not necessarily comparable to similarly-titled measures presented by other companies. We define cash burn as net cash used in operating activities plus acquired in-process research and development - milestone payments less proceeds from borrowings under financing agreement with TPG specifically related to our Phase 3 ATHENA trial. We believe cash burn to be a liquidity measure that provides useful information to management and investors about the amount of cash consumed by the operations of the business including milestone payments and proceeds from borrowings under the TPG financing agreement, which specifically offsets the costs of our ATHENA trial. A limitation of using this non-U.S. GAAP measure is that cash burn does not represent the total change in cash and cash equivalents for the period because it excludes all other cash provided by or used for other investing and financing activities. We account for this limitation by providing information about our investing and financing activities in the statements of cash flows in our financial statements and by presenting cash flows from investing and financing activities in our reconciliation of cash burn. In addition, it is important to note that other companies, including companies in our industry, may not use cash burn, may calculate cash burn in a different manner than we do or may use other financial measures to evaluate their performance, all of which could reduce the usefulness of cash burn as a comparative measure. Because of these limitations, cash burn should not be considered in isolation from, or as a substitute for, financial information prepared in accordance with U.S. GAAP.

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