

## Clovis Oncology Announces Second Quarter 2021 Operating Results

8/4/2021

- \$36.8M in Rubraca® (rucaparib) global net product revenues for Q2 2021, down 8% vs. Q2 2020, due to continuing impact of COVID-19
- Phase 1/2 LuMIERE clinical study of FAP-2286 open for enrollment, first peptide-targeted radionuclide therapeutic candidate targeting FAP in clinical development
- Three top-line Phase 3 data read-outs for Rubraca anticipated over the next six to 18 months with potential to address larger ovarian and prostate cancer patient populations in earlier lines of therapy
- \$72.5M in net proceeds raised through “at-the-market” equity offering program in Q2 2021
- \$230.2M in cash and cash equivalents and \$48.1M in available funding under the ATHENA financing at June 30, 2021
- \$33.1M or 30% reduction in R&D and SG&A expense and 22% reduction in net cash used in operating activities compared to Q2 2020

BOULDER, Colo.--(BUSINESS WIRE)-- **Clovis Oncology**, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended June 30, 2021, and provided an update on the Company's **clinical development programs** and regulatory and commercial outlook for the rest of the year.

“While these are obviously complicated times, I’m encouraged that, based on the data available to us, we have maintained our US market share for Rubraca and achieved meaningful growth in Europe in the second-line maintenance ovarian cancer setting, and significantly advanced our development and pipeline programs during the quarter,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “Importantly, in the next six to 18 months, we expect three Phase 3 data read-outs for Rubraca, potentially expanding the number of ovarian and prostate cancer patients eligible for Rubraca treatment in the US and Europe, which we anticipate will drive growth in sales. In addition, we achieved a significant milestone in the second quarter with the initiation of our Phase 1/2 LuMIERE clinical study of FAP-2286, the first peptide-targeted radionuclide therapeutic targeting FAP in clinical development. This represents the first of multiple anticipated milestones in our strategy to develop innovative precision-targeted radiotherapies for a broad range of tumors.”

### Second Quarter 2021 Financial Results

Clovis reported global net product revenues for Rubraca of \$36.8 million for Q2 2021, which included US product

revenues of \$27.7 million and ex-US product revenues of \$9.1 million, respectively. This represents an 8% decrease year-over-year, compared to Q2 2020 net product revenues of \$39.9 million, which included US net product revenues of \$36.7 million and ex-US net product revenues of \$3.2 million. The decrease was primarily due to fewer diagnoses and fewer patient starts, due to the ongoing COVID-19 pandemic.

Clovis reported net product revenue for Rubraca of \$74.9 million for the six months ended June 30, 2021, which included US product revenue of \$59.4 million and ex-U.S. product revenue of \$15.5 million, compared to net product revenue for same period in 2020 of \$82.5 million, which included US net product revenue of \$76.0 million and ex-US net product revenue of \$6.5 million.

Research and development expenses totaled \$45.8 million for Q2 2021, down 35% compared to \$69.9 million for the comparable period in 2020, due primarily to lower spending on Rubraca clinical trials. For the six months ended June 30, 2021, research and development expenses totaled \$98.6 million, down 29% compared to \$138.1 million for the comparable period in 2020. As previously discussed, the Company expects research and development expenses to be lower in the full year 2021 compared to 2020.

Selling, general and administrative expenses totaled \$32.9 million for Q2 2021, down 21% compared to \$41.9 million for the comparable period in 2020, due to overall cost reduction efforts. For the six months ended June 30, 2021, selling, general and administrative expenses totaled \$62.9 million, down 26% compared to \$84.5 million for the comparable period in 2020. Clovis continues to expect selling, general and administrative expenses to decrease in the full year 2021 compared to 2020.

Clovis reported a net loss for Q2 2021 of \$66.4 million, or (\$0.61) per share, compared to a net loss for Q2 2020 of \$92.2 million, or (\$1.15) per share. Net loss for Q2 2021 included share-based compensation expense of \$7.4 million, compared to \$13.3 million for the comparable period of 2020.

Clovis had \$230.2 million in cash and cash equivalents as of June 30, 2021. During Q2 2021, the Company raised \$72.5 million in net proceeds through its “at-the-market” equity offering program.

As of June 30, 2021, the Company had drawn \$126.9 million under the Sixth Street Partners, LLC (SSP) ATHENA clinical trial financing and had up to \$48.1 million available to draw under the agreement to fund the expenses of the ATHENA trial.

Net cash used in operating activities was \$46.8 million for Q2 2021, down 22% from the \$59.9 million reported in Q2 2020. Net cash used in operating activities for the first six months of 2021 was \$108.6 million, down 24% from the same period in 2020.

Cash burn in Q2 2021 was \$33.4 million, down 33% from \$50.1 million in Q2 2020. Cash burn for the first six months of 2021 was \$81.5 million, down 30% from \$117.0 million in the first six months of 2020.

## Clovis Oncology Pipeline Highlights

### Three Anticipated Rubraca Phase 3 Read-outs in Next 6 to 18 Months

Top-line data from the ATHENA Phase 3 study in first-line maintenance treatment ovarian cancer setting evaluating Rubraca monotherapy versus placebo are now expected in the first quarter of 2022 based on event-based projections. Data from the combination arm of Rubraca plus Opdivo® (nivolumab) versus Rubraca monotherapy are expected in the second half of 2022 based on protocol-defined assumptions.

Top-line data from the TRITON3 trial, which is expected to serve as the confirmatory study for Rubraca's approval in metastatic castration-resistant prostate cancer (mCRPC) as well as a potential second-line label expansion, are expected in the second quarter of 2022. TRITON3 is a Phase 3 study evaluating Rubraca versus physician's choice of chemotherapy or second-line androgen deprivation therapy in patients with mCRPC with BRCA and ATM mutations.

The three anticipated data readouts, ATHENA monotherapy, ATHENA combination and TRITON3, provide the potential to reach larger patient populations in earlier lines of therapy for ovarian and prostate cancers, in which Rubraca is currently approved in later-line indications. The timing for each data readout is contingent upon the occurrence of the protocol-specified progression-free survival (PFS) events.

### LuMIERE Phase 1/2 Study of FAP-2286 Now Opened for Enrollment

FAP-2286 is Clovis Oncology's peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein (FAP) and is the lead candidate in the Company's TRT development program. Following FDA clearance of each of the treatment and imaging IND applications for FAP-2286, Clovis opened enrollment for the Phase 1/2 LuMIERE clinical study. The Phase 1 portion of the LuMIERE study will evaluate the safety of the FAP-targeting investigational therapeutic agent and identify the recommended Phase 2 dose and schedule of lutetium-177 labeled FAP-2286 (<sup>177</sup>Lu-FAP-2286). FAP-2286 labeled with gallium-68 (<sup>68</sup>Ga-FAP-2286) will be used as an investigational imaging agent to identify patients with FAP-positive tumors appropriate for treatment in LuMIERE. Once the Phase 2 dose is determined, Phase 2 expansion cohorts are planned in multiple tumor types.

### Conference Call Details

Clovis will hold a conference call this morning, August 4, at 8:30 a.m. ET to discuss Q2 2021 results and provide an update on the Company's clinical development programs and regulatory and commercial outlook for the rest of the

year. The conference call will be simultaneously webcast on the Clovis Oncology website at [clovisoncology.com](http://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: 3887398.

## About Rubraca (rucaparib)

Rubraca is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in 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 US 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. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca. 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 the US and Europe.

## About FAP-2286

FAP-2286 is a clinical candidate under investigation as a peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein (FAP). FAP-2286 consists of two functional elements; a targeting peptide

that binds to FAP and a site that can be used to attach radioactive isotopes for imaging and therapeutic use. FAP is highly expressed on cancer-associated fibroblasts (CAFs) in many epithelial cancers, including more than 90% of breast, lung, colorectal, and pancreatic carcinomas.<sup>i</sup> Clovis holds US and global rights for FAP-2286 excluding Europe, Russia, Turkey, and Israel.

FAP-2286 is an unlicensed medical product.

## About Targeted Radionuclide Therapy

Targeted radionuclide therapy is an emerging class of cancer therapeutics, which seeks to deliver radiation directly to the tumor while minimizing delivery of radiation to normal tissue. Targeted radionuclides are created by linking radioactive isotopes, also known as radionuclides, to targeting molecules (e.g., peptides, antibodies, small molecules) that can bind specifically to tumor cells or other cells in the tumor environment. Based on the radioactive isotope selected, the resulting agent can be used to image and/or treat certain types of cancer. Agents that can be adapted for both therapeutic and imaging use are known as “theranostics.” Clovis is developing a pipeline of novel, targeted radiotherapies for cancer treatment and imaging, including its lead candidate, FAP-2286, an investigational peptide-targeted radionuclide therapeutic (PTRT) and imaging agent, as well as three additional discovery-stage compounds.

## About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical company focused on acquiring, developing, and commercializing innovative anti-cancer agents in the US, 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 US and Europe. Please visit [www.clovisoncology.com](http://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, 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, 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 Sixth Street Partners, LLC. 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 timing and extent of recovery from the impact of COVID-19, 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.

i Rettig WJ et al. Regulation and Heteromeric Structure of the Fibroblast Activation Protein in Normal and Transformed Cells of Mesenchymal and Neuroectodermal Origin. Cancer Res. 1993;53:3327-3335.

CLOVIS ONCOLOGY, INC  
CONSOLIDATED FINANCIAL RESULTS  
(Unaudited, in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Product revenue	\$ 36,820	\$ 39,887	\$ 74,873	\$ 82,451
Operating expenses:				
Cost of sales - product	8,294	9,120	16,562	18,216
Cost of sales - intangible asset amortization	1,343	1,280	2,686	2,492
Research and development	45,759	69,878	98,564	138,099
Selling, general and administrative	32,918	41,902	62,859	84,500
Acquired in-process research and development	2,204	-	2,204	-
Other operating expenses	3,884	355	7,591	3,805
Total expenses	94,402	122,535	190,466	247,112
Operating loss	(57,582)	(82,648)	(115,593)	(164,661)
Other income (expense):				
Interest expense	(8,770)	(6,739)	(16,807)	(16,300)
Foreign currency (loss) gain	(206)	142	(752)	(735)
Loss on convertible notes conversion	-	-	-	(7,791)
Loss on extinguishment of debt	-	(3,277)	-	(3,277)
Other income	107	239	290	1,081
Other income (expense), net	(8,869)	(9,635)	(17,269)	(27,022)
Loss before income taxes	(66,451)	(92,283)	(132,862)	(191,683)
Income tax (expense) benefit	3	36	137	104
Net loss	\$ (66,448)	\$ (92,247)	\$ (132,725)	\$ (191,579)
Basic and diluted net loss per common share	\$ (0.61)	\$ (1.15)	\$ (1.25)	\$ (2.52)
Basic and diluted weighted-average common shares	108,481	80,453	106,375	76,057

CONSOLIDATED BALANCE SHEET DATA  
(Unaudited, in thousands)

	June 30, 2021	Dec 31, 2020
Cash and cash equivalents	\$ 230,204	\$ 240,229
Working capital	122,474	125,901
Total assets	572,229	605,554
Convertible senior notes	500,112	499,044
Common stock and additional paid-in capital	2,582,839	2,498,283
Total stockholders' deficit	(206,983)	(158,748)

Other Data  
(Unaudited, in thousands)

	Six Months Ended June 30,	
	2021	2020
Net cash used in operating activities	\$ (108,645)	\$ (142,351)
Share Based Compensation Expense	\$ 11,401	\$ 26,274

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net cash used in operating activities	\$ (46,755)	\$ (59,857)	\$ (108,645)	\$ (142,351)
Adjustments:				
Acquired in-process research and development - milestone payment	-	(8,000)	-	(8,000)
Proceeds from borrowings under financing agreement	13,351	17,730	27,154	33,322
Cash burn	<u>\$ (33,404)</u>	<u>\$ (50,127)</u>	<u>\$ (81,491)</u>	<u>\$ (117,029)</u>
Net cash (used in) provided by investing activities	\$ (36)	\$ 56,800	\$ (154)	\$ 126,607
Net cash provided by financing activities	\$ 85,940	\$ 101,007	\$ 99,316	\$ 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 less proceeds from borrowings under financing agreement with Sixth Street 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 proceeds from borrowings under the Sixth Street 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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