



NEWS RELEASE

Clovis Oncology Announces 2020 Operating Results

2/23/2021

- \$164.5M in Rubraca® (rucaparib) global net product revenues for 2020, up 15% over 2019; \$43.3M in Rubracaglobal net product revenues for Q4 2020, up 10% over Q4 2019
- Phase 1/2 LuMIERE study of FAP-2286, a targeted radiotherapy, planned to begin 1H 2021
- Top-line data from Phase 3 ATHENA trial of Rubraca as first-line maintenance ovarian cancer monotherapy anticipated 2H 2021
- Interim data from Phase 2 cohorts of LIO-1 study of lucitanib in combination with Opdivo® (nivolumab) in gynecologic cancers anticipated at 2021 medical meetings
- Net cash used in operating activities significantly lower in 2020 compared to 2019
- \$240.2M in cash and cash equivalents at December 31, 2020, which is anticipated to fund the Company's operating plan into early 2023 based on current revenue and expense forecasts

BOULDER, Colo.--(BUSINESS WIRE)-- **Clovis Oncology**, Inc. (NASDAQ:CLVS) reported financial results for the quarter and year ended December 31, 2020, and provided an update on the Company's **clinical development programs** and regulatory and commercial outlook for 2021.

"Despite the evident COVID-related challenges of 2020, we are pleased with our overall sales performance and pipeline progress," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "Most importantly, we advanced our development programs in 2020, positioning them for important potential achievements in 2021, including the initiation of clinical development for FAP-2286 in the first half of the year, top-line ATHENA monotherapy data in the second half of the year and initial efficacy data for the LIO-1 lucitanib and Opdivo combination trial at medical meetings later this year. While early, we are increasingly enthusiastic about FAP-2286 and our commitment to becoming a leader in the emerging field of targeted radionuclide therapy."

Fourth Quarter and Year-End 2020 Financial Results

Clovis reported global net product revenues for Rubraca of \$43.3 million for the fourth quarter of 2020, which included U.S. product revenues of \$36.4 million and ex-U.S. product revenues of \$6.9 million, respectively. This represents a 10 percent increase year-over-year compared to Q4 2019 net product revenues of \$39.3 million, which included U.S. net product revenues of \$36.1 million and ex-U.S. net product revenues of \$3.2 million.

Rubraca global net product revenues for 2020 were \$164.5 million, which included \$146.3 million in the U.S. and \$18.2 million in ex-U.S. product revenues, respectively. This represents a 15 percent increase year-over-year compared to 2019 net product revenues of \$143.0 million, which included \$137.2 million in the U.S. and ex-U.S. net product revenues of \$5.8 million.

Research and development expenses totaled \$56.7 million for Q4 2020 and \$257.7 million for FY 2020, down 22 percent and 9 percent, respectively, compared to \$72.5 million and \$283.1 million for the comparable periods in 2019. Research and development expenses decreased for the quarter and year compared to the same periods in the prior year due primarily to lower spending on Rubraca clinical trials. We expect research and development expenses to be lower in the full year 2021 compared to 2020.

Selling, general and administrative expenses totaled \$40.8 million for Q4 2020 and \$163.9 million for FY 2020, both down 10 percent compared to \$45.2 million and \$182.8 million for the comparable periods in 2019. Selling, general and administrative expenses decreased during the quarter and year compared to the same periods in the prior year with savings due to the COVID-19 situation globally and overall cost reduction efforts. We expect selling, general and administrative expenses to decrease in the full year 2021 compared to 2020.

Clovis reported a net loss for the fourth quarter of 2020 of \$99.0 million, or (\$1.02) per share, and a net loss of \$369.2 million, or (\$4.38) per share, for FY 2020. Net loss for Q4 2019 was \$99.5 million, or (\$1.81) per share, and \$400.4 million, or a net loss of (\$7.43) per share, for FY 2019. Net loss for Q4 and FY 2020 included share-based compensation expense of \$12.0 million and \$50.8 million, compared to \$12.6 million and \$54.3 million for the comparable periods of 2019.

Clovis had \$240.2 million in cash and cash equivalents as of December 31, 2020, which is expected to fund the Company's operating plan into early 2023 based on current revenue and expense forecasts.

As of December 31, 2020, the Company had drawn approximately \$100 million under the Sixth Street Partners, LLC ATHENA clinical trial financing and had up to \$75 million available to draw under the agreement to fund the expenses of the ATHENA trial.

Net cash used in operating activities was \$56.1 million for the fourth quarter of 2020, down from \$70.1 million

reported in the fourth quarter of 2019. Similarly, net cash used in operating activities for FY 2020 was \$252.7 million, compared with \$323.6 million for FY 2019. Cash burn in Q4 2020 was \$40.9 million, down 27 percent from the Q4 2019 quarter cash burn of \$56.3 million. Cash burn for the twelve months ended December 31, 2020 was \$195.6M million, down 36 percent from the twelve months ended 2019 cash burn of \$304.7 million. We expect this trend of lower cash burn to continue in 2021.

Clovis Oncology Pipeline Highlights

Rubraca ARIEL4 Study Met Primary Endpoint of Improved PFS Compared to Chemotherapy

In December, Clovis announced the top line results of the ARIEL4 randomized Phase 3 study of Rubraca versus standard-of-care chemotherapy, in which Rubraca met the primary endpoint of significantly improving progression-free survival (PFS) in later-line ovarian cancer patients with a BRCA mutation. The safety observed in the study was highly consistent with both the U.S. and European labels. These results were submitted as a late-breaking abstract and accepted as an oral presentation at the upcoming Society for Gynecologic Oncology Virtual Annual Meeting in March. Completion of ARIEL4 is a post-marketing commitment in the U.S. and Europe.

Anticipated Rubraca Pipeline Events in 2021

Top-line data from the ATHENA Phase 3 study in first-line maintenance treatment ovarian cancer setting evaluating Rubraca monotherapy versus placebo are expected in the second-half of 2021, contingent on achieving sufficient PFS events. Data from the combination arm of Rubraca plus Opdivo versus Rubraca monotherapy are expected a year or more later.

LODESTAR, the Company's Phase 2 trial of Rubraca in patients with solid tumors with deleterious mutations in homologous recombination repair (HRR) genes is currently enrolling. This study may be registration-enabling with a potential regulatory filing by the end of 2021 or first-half 2022.

LuMIERE Phase 1/2 Study of FAP-2286 Expected to Begin 1H 2021

FAP-2286 is Clovis Oncology's peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein (FAP) and represents its lead candidate in the PTRT development program. Clovis intends to initiate the Phase 1/2 LuMIERE clinical study of lutetium-177 labeled FAP-2286 (¹⁷⁷Lu-FAP-2286) to determine the dose and tolerability of the FAP-targeting therapeutic agent (Phase 1), with expansion cohorts planned in multiple tumor types (Phase 2). FAP-2286 labelled with gallium-68 (⁶⁸Ga-FAP-2286) will be utilized as a diagnostic to identify patients with FAP-positive tumors appropriate for treatment with the therapeutic agent. The LuMIERE study is expected to begin in the first half of 2021, pending acceptance by the FDA of gallium-68 CMC data from clinical

sites. Other studies of FAP-2286 linked to an alpha-particle emitting radionuclide and combination studies are also being planned.

Interim LIO-1 data of Lucitanib and Opdivo in Combination Expected in 2021

The Phase 2 part of the LIO-1 study of lucitanib in combination with Opdivo continues to enroll patients with gynecologic cancers, and Clovis Oncology intends to present initial data at 2021 medical meetings, which are expected to include interim results from the ovarian and endometrial cancer expansion cohorts.

Conference Call Details

Clovis will hold a conference call to discuss Q4/FY 2020 results this morning, February 23, at 8:30am 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: 5869256.

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. 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 of the U.S. and Europe.

About Lucitanib

Lucitanib is an investigational angiogenesis inhibitor, which inhibits 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. Clovis holds global rights for lucitanib excluding China.

Lucitanib is an unlicensed medical product.

About FAP-2286

FAP-2286 is a preclinical candidate under investigation as a peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein (FAP). FAP-2286 consists of two parts; a peptide that binds to FAP and a linker and site that can be used to attach radiation for imaging and therapeutic use. FAP is highly expressed in many epithelial cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas. Clovis holds U.S. and global rights for FAP-2286 excluding Europe, Russia, Turkey, and Israel.

FAP-2286 is an unlicensed medical product.

About Peptide-Targeted Radionuclide Therapy

Peptide-targeted radionuclide therapy (PTRT) is a form of targeted radiotherapy that is emerging as a new treatment option for patients with cancer. These therapies consist of a small amount of a radioactive isotope, known as a radionuclide, linked to a cell-targeting peptide that binds to a cancer specific protein which selectively directs the radionuclide to tumors. Following binding, the radionuclide warhead emits ionizing radiation causing DNA damage and cell death to neighboring tumor cells.

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, 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, 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 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 December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Product revenue	\$ 43,299	\$ 39,307	\$ 164,522	\$ 143,006
Operating expenses:				
Cost of sales - product	9,474	7,942	36,128	29,926
Cost of sales - intangible asset amortization	1,342	1,211	5,177	4,760
Research and development	56,706	72,473	257,707	283,146
Selling, general and administrative	40,758	45,168	163,894	182,769
Acquired in-process research and development	-	-	-	9,440
Other operating expenses	-	4,172	3,804	9,711
Total expenses	108,280	130,966	466,710	519,752
Operating loss	(64,981)	(91,659)	(302,188)	(376,746)
Other income (expense):				
Interest expense	(7,349)	(6,720)	(30,508)	(19,405)
Foreign currency gain (loss)	30	100	(72)	(547)
(Loss) gain on extinguishment of debt	-	-	(3,277)	18,480
Loss on convertible senior notes conversion	(27,284)	-	(35,075)	-
Legal settlement loss	-	-	-	(26,750)
Other income	202	1,262	1,361	6,342
Other income (expense), net	(34,401)	(5,358)	(67,571)	(21,880)
Loss before income taxes	(99,382)	(97,017)	(369,759)	(398,626)
Income tax benefit (expense)	425	(2,484)	547	(1,798)
Net loss	\$ (98,957)	\$ (99,501)	\$ (369,212)	\$ (400,424)
Basic and diluted net loss per common share	\$ (1.02)	\$ (1.81)	\$ (4.38)	\$ (7.43)
Basic and diluted weighted-average common shares	96,681	54,834	84,307	53,873

CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

	December 31, 2020	December 31, 2019
Cash and cash equivalents	\$ 240,229	\$ 161,833
Available-for-sale securities	-	134,826
Working capital	125,901	233,384
Total assets	605,554	669,604
Convertible senior notes	499,044	644,751
Common stock and additional paid-in capital	2,498,283	2,114,123
Total stockholders' deficit	(158,748)	(174,257)

Other Data
(Unaudited, in thousands)

	Twelve Months Ended December 31,	
	2020	2019
Net cash used in operating activities	(252,728)	(323,615)
Share Based Compensation Expense	50,794	54,304

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Net cash used in operating activities	\$ (56,053)	\$ (70,147)	\$ (252,728)	\$ (323,615)
Adjustments:				
Acquired in-process research and development - milestone payment	-	-	(8,000)	(15,750)
Proceeds from borrowings under financing agreement	15,156	13,828	65,119	34,636
Cash burn	\$ (40,897)	\$ (56,319)	\$ (195,609)	\$ (304,729)
Net cash (used in) provided by investing activities	\$ (260)	\$ 16,767	\$ 126,328	\$ 143,398
Net cash provided by financing activities	\$ 71,836	\$ 13,206	\$ 203,644	\$ 119,888

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 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 milestone payments and 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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