



NEWS RELEASE

Clovis Oncology Announces 2019 Operating Results

2/24/2020

- Rubraca® (rucaparib) net product revenue totaled \$143.0M for 2019 and \$39.3M for Q4 2019
- Net product revenue for 2019 up 50% over 2018
- 46% reduction in net cash utilized in 2H 2019 compared to 1H 2019
- \$296.7M in cash, cash equivalents and available for sale securities at December 31, 2019; continue to anticipate cash runway into 2H 2021
- Transaction in January 2020 reduced outstanding convertible debt at year-end 2019 by \$123.4M
- Supplemental NDA for Rubraca in patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer granted Priority Review by FDA with PDUFA date of May 15, 2020
- Lucitanib combination studies enrolling; initial data anticipated at medical meetings in 2020
- Acquired rights to FAP-2286, a radiopharmaceutical therapy targeting FAP; plan to submit an IND in 2H 2020

BOULDER, Colo.--(BUSINESS WIRE)-- **Clovis Oncology**, Inc. (NASDAQ:CLVS) reported financial results for the quarter and year ended December 31, 2019, and provided an update on Clovis' **clinical development programs** and regulatory and commercial outlook for 2020.

"This is an encouraging time for Clovis, as we launch Rubraca in multiple European countries in the recurrent ovarian cancer maintenance indication and prepare for a potential U.S. approval and launch of Rubraca in patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer," said Patrick J. Mahaffy, CEO and President of Clovis Oncology. "We also look forward to initial clinical data from lucitanib combination studies later this year, and initiating clinical development with FAP-2286, our peptide-targeted radiopharmaceutical therapy product candidate. This program, as well as our ongoing discovery collaboration with 3B Pharmaceuticals, provides us an exciting opportunity to be a leader in an important new area of oncology drug development."

Fourth Quarter and Year-End 2019 Financial Results

Clovis reported net product revenue for Rubraca of \$39.3 million for Q4 2019, which included U.S. net product

revenue of \$36.1 million and ex-U.S. net product revenue of \$3.2 million. This represents a five percent increase sequentially and 30 percent year over year compared to net product revenues for Q3 2019 and Q4 2018 of \$37.6 million and \$30.4 million, respectively. U.S. net product revenues were in line with the \$36.5 million reported in Q3 2019 and ex-U.S. net product revenues increased \$2.1 million over Q3 2019.

The supply of free drug distributed to eligible patients in the U.S. through the Rubraca patient assistance program for Q4 2019 was 18 percent of the overall U.S. commercial supply, compared to 20 percent in Q3 2019 and 26 percent reported in Q4 2018. This represented \$8.0 million in commercial value for Q4 2019 compared to \$9.0 million in Q3 2019 and \$10.4 million in Q4 2018.

Net product revenue for 2019 was \$143.0 million, which included \$137.2 million in the U.S. and \$5.8 million in ex-U.S. product revenues, respectively. This represents a 50 percent increase year-over-year compared to net product revenue of \$95.4 million in 2018, all of which were in the U.S. For the full year ended December 31, 2019 the supply of free drug distributed to eligible patients was approximately 20 percent of the overall U.S. commercial supply compared to 26 percent in 2018. This represented \$34.8 million in commercial value for the full year 2019, compared to \$33.4 million for 2018.

Clovis had \$296.7 million in cash, cash equivalents and available-for-sale securities as of December 31, 2019.

In August 2019, Clovis repurchased \$190.3 million aggregate principal amount of its 2.50% convertible senior notes due 2021. Approximately \$97.2 million aggregate principal amount of these notes remain outstanding.

In January 2020, Clovis repurchased \$123.4 million aggregate principal amount of its 4.50% convertible senior notes due 2024 that were initially issued in August 2019. This transaction will save \$28 million in cash on interest payments under the notes issued in August 2019, and approximately \$140.0 million aggregate principal amount of these notes remain outstanding. Additionally, the Company has \$300 million aggregate principal amount outstanding of its 1.25% convertible senior notes due 2025.

As of December 31, 2019, the Company had drawn approximately \$35 million under the TPG ATHENA clinical trial financing and had up to \$140 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, cash equivalents and available-for-sale securities, the Company believes it has sufficient cash, cash equivalents and available-for-sale securities to fund its operating plan into the second half of 2021. This does not include any cash repayment that may be required to pay off (unless refinanced earlier) the remaining \$97.2 million aggregate principal amount of the 2.50% convertible notes due 2021, at their maturity in September 2021.

Net cash used in operating activities was \$70.1 million for Q4 2019 and \$323.6 million for the full year 2019, compared with \$82.7 million and \$366.0 million for the comparable periods in 2018. Borrowings under the TPG ATHENA financing provided \$13.8 million in Q4 2019, reducing net cash utilized in operating activities to \$56.3 million in Q4 2019. Net cash used in operating activities for Q4 2019 included an upfront payment of \$9.4 million to 3B Pharmaceuticals related to the in-licensing of FAP-2286.

Net cash used in operating activities was \$127.1 million for the second half of 2019, and \$196.5 million for the first half of 2019, a reduction of \$69.4 million or 35 percent. In addition, borrowings under the TPG ATHENA financing provided \$8.6 million in the first half and \$26.0 million in the second half of 2019, reducing net cash utilized in operating activities by \$86.8 million, or 46 percent, from the first half to second half of 2019.

Clovis reported a net loss for Q4 2019 of \$99.5 million, or (\$1.81) per share, and \$400.4 million, or a net loss of (\$7.43) per share for the full year 2019. Net loss for Q4 2018 was \$99.3 million, or (\$1.88) per share, and \$368.0 million, or a net loss of (\$7.07) per share, for the full year 2018. Net loss for Q4 and the full year 2019 included share-based compensation expense of \$12.6 million and \$54.3 million, compared to \$11.4 million and \$49.1 million for the comparable periods of 2018.

Research and development expenses totaled \$72.5 million for Q4 2019 and \$283.1 million for the full year 2019, compared to \$71.2 million and \$231.3 million for the comparable periods in 2018. The increase for the full year is primarily due to higher research and development costs for rucaparib clinical trials.

Selling, general and administrative expenses totaled \$45.2 million for Q4 2019 and \$182.8 million for the full year 2019, compared to \$49.1 million and \$175.8 million for the comparable periods in 2018. Selling, general and administrative expenses increased for the full year due to commercialization activities for Rubraca including increased costs associated with building out the European commercial infrastructure.

European Launch of Rubraca in Ovarian Cancer

In January 2019, the European Commission granted a variation to the marketing authorization for Rubraca to include 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. Following successful reimbursement negotiations in each country, commercial launches of Rubraca are underway in each of Germany, England, Italy and France and planned in Spain shortly.

U.S. Supplemental New Drug Application for Rubraca in BRCA1/2-mutant Advanced Prostate Cancer

In November 2019, Clovis submitted the planned supplemental New Drug Application (sNDA) for Rubraca as a monotherapy treatment of adult patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer to the Food and Drug Administration (FDA). The sNDA filing was based on data from the TRITON clinical program in advanced prostate cancer. In January 2020, Clovis announced that the FDA accepted the Company's sNDA for Rubraca and granted priority review status to the application with a Prescription Drug User Fee Act (PDUFA) date of May 15, 2020.

Conference Call Details

Clovis will hold a conference call to discuss Q4/FY 2019 results this afternoon, February 24, 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 (866) 393-4306, International participants (734) 385-2616, conference ID: 1255036.

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, and lung cancers. 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.

In the EU, 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. This expands rucaparib's indication beyond its initial marketing authorization in the EU granted in May 2018 and with this label expansion, rucaparib is now available to patients regardless of their BRCA mutation status. Rubraca is also approved in the EU 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 the EU.

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 reverses this immunosuppression and can 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 (PTRT) 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 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 uncertainties inherent in the effect our future revenues 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.

(Unaudited, in thousands, except per share amounts)

	Three Months Ended December 31, Twelve Months Ended December 31,			
	2019	2018	2019	2018
Revenues:				
Product revenue, net	\$ 39,307	\$ 30,351	\$ 143,006	\$ 95,388
Operating expenses:				
Cost of sales - product	7,942	6,182	29,926	19,444
Cost of sales - intangible asset amortization	1,211	778	4,760	2,630
Research and development	72,473	71,210	283,146	231,347
Selling, general and administrative	45,168	49,148	182,769	175,781
Acquired in-process research and development	-	-	9,440	-
Other operating expenses	4,172	-	9,711	-
Total expenses	130,966	127,318	519,752	429,202
Operating loss	(91,659)	(96,967)	(376,746)	(333,814)
Other income (expense):				
Interest expense	(6,720)	(3,591)	(19,405)	(13,183)
Foreign currency gain (loss)	100	(312)	(547)	(346)
Legal settlement loss	-	-	(26,750)	(27,975)
Gain on extinguishment of debt	-	-	18,480	-
Other income	1,262	2,497	6,342	7,917
Other income (expense), net	(5,358)	(1,406)	(21,880)	(33,587)
Loss before income taxes	(97,017)	(98,373)	(398,626)	(367,401)
Income tax expense	(2,484)	(888)	(1,798)	(608)
Net loss	\$ (99,501)	\$ (99,261)	\$ (400,424)	\$ (368,009)
Basic and diluted net loss per common share	\$ (1.81)	\$ (1.88)	\$ (7.43)	\$ (7.07)
Basic and diluted weighted-average common shares outstanding	54,834	52,724	53,873	52,066

CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

	December 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 161,833	\$ 221,876
Available-for-sale securities	134,826	298,270
Working capital	233,384	446,550
Total assets	669,604	863,560
Convertible senior notes	644,751	575,470
Common stock and additional paid-in capital	2,114,123	2,034,195
Total stockholders' (deficit) equity	(174,257)	146,469

Other Data
(Unaudited, in thousands)

	Twelve Months Ended December 31,	
	2019	2018
Net cash used in operating activities	(323,615)	(365,997)
Share Based Compensation Expense	54,304	49,090

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Breanna Burkart

303.625.5023

bburkart@clovisoncology.com

Anna Sussman

303.625.5022

asussman@clovisoncology.com

Source: Clovis Oncology, Inc.

