Curis Reports Second Quarter 2019 Financial Results

- Anti-tumor activity observed in multiple patients in initial data from the ongoing Phase 1 study of CA-4948 in non-Hodgkin Lymphoma -

- Management to host conference call today at 4:30 p.m. ET -

LEXINGTON, Mass., Aug. 6, 2019 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today reported its financial results for the second quarter ended June 30, 2019.

"Today, we are excited to announce initial data from our ongoing Phase 1 study of CA-4948 in patients with non-Hodgkin lymphoma, demonstrating anti-cancer activity for CA-4948 with tumor reduction observed in multiple patients across multiple dose levels," said James Dentzer, President and Chief Executive Officer of Curis. "We are especially pleased to see such encouraging results, as we are still in the middle of the dose optimization phase of the study. As a result of this positive readout, we are announcing today our decision to advance CA-4948 into the clinic in a new study of patients with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS). We look to provide more detailed guidance on the timing of that study later this year."

"I am very pleased with the initial data we are seeing in our ongoing Phase 1 trial of CA-4948," said Robert Martell, Head of R&D of Curis. "As we increase dosing, we have observed continued evidence of pharmacodynamic target inhibition with dose-proportional increases in pharmacokinetic exposure. With the caveats of small cohort sizes and low initial dosage levels, we found patients experienced anti-tumor activity at multiple doses, including two of the patients at the 200mg BID dose level. And, importantly, all of these findings have been observed at tolerable dose levels. We look forward to reporting additional data in this ongoing study at an upcoming medical conference."

Separately, ongoing clinical studies of fimepinostat and CA-170 remain on track to provide initial data, for both studies, later this year.

Second Quarter 2019 and Recent Operational Highlights

Precision oncology, fimepinostat (HDAC/PI3K inhibitor):

Curis has initiated a Phase 1 study of fimepinostat (a MYC suppressor) with venetoclax (a BCL-2 inhibitor) combination regimen in diffuse large B-cell lymphoma (DLBCL), including patients with double-hit/double-expressor (DH/DE) lymphoma, or High-Grade B-Cell Lymphoma (HGBL). In preclinical models, fimepinostat administered in combination with venetoclax resulted in an enhanced benefit relative to each agent alone.

Precision oncology, CA-4948 (IRAK4 Inhibitor; Aurigene collaboration):

Today, Curis announced initial safety and efficacy data from its Phase 1 dose escalation study of CA-4948 in patients with non-Hodgkin lymphoma, including those with MYD88 alterations. As previously reported, the Phase 1 study of CA-4948 has advanced through five dose levels and is now being studied at exposures that resulted in anticancer efficacy in preclinical animal models. In the ongoing Phase 1 study, CA-4948 has demonstrated pharmacokinetic activity linearly-associated with dosing and clear signs of pharmacodynamic inhibition of the target. In addition, tumor burden reduction was observed in multiple patients across multiple dose levels with an acceptable safety profile. Treatment with CA-4948 at 200mg twice-daily (BID) is generally safe and well-tolerated, with no dose-limiting toxicities (DLTs) observed. The Company is currently enrolling patients in the study at 400mg BID and plans to continue dose escalation in the study to determine the optimal dose for clinical development.

Today, Curis announced that it will initiate a separate Phase 1 trial of CA-4948 in patients with AML and MDS. In June 2019, the Company highlighted a publication in *Nature Cell Biology* showing that a cancer-causing splicing variant of IRAK4 (IRAK4-L) is dominant in the majority of cases of AML and MDS. In addition, specific mutations of the U2AF1 splicing factor induce IRAK4-L, which has potential therapeutic targetability by CA-4948. The findings present the inhibition of IRAK4 as a potential treatment option for patients with myeloid malignancies expressing IRAK4-L and with U2AF1 mutations.

Immuno-oncology, CA-170 (VISTA / PDL1 antagonist; Aurigene collaboration):

Phase 1 study of CA-170 in mesothelioma patients (high VISTA expressors) is ongoing. The trial completed enrollment in May 2019.

Upcoming 2019 Milestones

Report update of initial safety and efficacy data from the Phase 1 dose escalation study of CA-4948 in patients with NHL at an upcoming medical conference.

Report initial safety data from the Phase 1 study of the combination of fimepinostat and venetoclax regimen in patients with R/R DLBCL, including patients with DH/DE lymphoma, or HGBL, in the second half of 2019.

Report initial efficacy data from the Phase 1 study of CA-170 in patients with mesothelioma in the second half of 2019.

Second Quarter 2019 Financial Results

Curis reported a net loss of $7.2 million, or $0.22 per share on both a basic and diluted basis for the second quarter of 2019, as compared to a net loss of $8.7 million, or $0.26 per share on both a basic and diluted basis for the same period in 2018. Curis reported a net loss of $17.1 million, or $0.52 per share, on both a basic and diluted basis for the six months ended June 30, 2019, as compared to a net loss of $19.4 million, or $0.59 per share on both a basic and diluted basis for the same period in 2018.

Revenues for the second quarter of 2019 were $2.1 million, as compared to $2.4 million for the same period in 2018. Revenues for the six months ended June 30, 2019 were $3.9 million, as compared to $4.8 million for the same period in 2018. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®.

Operating expenses were $8.2 million for the second quarter of 2019, as compared to $10.2 million for the same period in 2018. Operating expenses for the six months ended June 30, 2019 were $15.6 million, as compared to $22.6 million for the same period in 2018, and comprised the following:

Costs of Royalty Revenues. Costs of royalty revenues, primarily amounts due to third-party university patent licensors in connection with Genentech and Roche's Erivedge net sales, were $0.1 million for both the second quarter of 2019 and 2018. Cost of royalty revenues for the six months ended June 30, 2019 were $0.2 million, as compared to $0.3 million for the same period in 2018.

Research and Development Expenses (R&D). R&D expenses were $5.6 million for the second quarter of 2019, as compared to $6.5 million for the same period in 2018. The decrease was primarily driven by lower employee related expenses partially offset by an overall increase in direct research and development expenses. R&D expenses were $9.7 million for the six months ended June 30, 2019 as compared to $14.7 million for the same period in 2018.

General and Administrative Expenses (G&A). G&A expenses were $2.5 million for the second quarter of 2019 as compared to $3.6 million for the same period in 2018. The decrease was primarily driven by lower personnel, legal services and stock-based compensation during the period. G&A expenses were $5.7 million for the six months ended June 30, 2019, as compared to $7.6 million for the same period in 2018.

Other Expenses. Net other expense for the second quarter 2019 was $1.1 million, as compared to $0.8 million for the same period in 2018. Net other expense for the second quarter 2019 primarily consisted of non-cash imputed interest expense related to future royalty payments, whereas in 2018 the expense related to interest accrued on Curis Royalty's debt obligations. Other expense, net was $5.4 million and $1.6 million for the six months ended June 30, 2019 and 2018, respectively.

As of June 30, 2019, Curis's cash, cash equivalents, marketable securities and investments totaled $35.3 million and there were approximately 33.2 million shares of common stock outstanding.

Conference Call Information

Curis management will host a conference call today, August 6, 2019, at 4:30 p.m. EDT, to discuss these financial results, as well as provide a corporate update.

To access the live conference call, please dial 1-888-346-6389 from the United States or 1-412-317-5252 from other locations, shortly before 4:30 p.m. EDT. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section.

About Curis, Inc.

Curis is a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, including fimepinostat, which is being investigated in clinical studies in patients with DLBCL and solid tumors. Curis is also engaged in a collaboration with Aurigene to develop first-in-class therapeutics in immuno-oncology and precision oncology. As part of this collaboration, Curis has exclusive licenses to oral small molecule antagonists of immune checkpoints including, the VISTA/PDL1 antagonist CA-170, and the TIM3/PDL1 antagonist CA-327, as well as the IRAK4 kinase inhibitor, CA-4948. CA-170 is currently undergoing testing in a Phase 1 trial in patients with mesothelioma and in a Phase 2 trial in patients with advanced solid tumors and lymphomas in India conducted by Aurigene. CA-4948 is currently undergoing testing in a Phase 1 trial in patients with non-Hodgkin lymphoma. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are commercializing Erivedge® for the treatment of advanced basal cell carcinoma.

For more information, visit Curis's website at www.curis.com.

Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including without limitation statements regarding any expectations of revenue, expenses, earnings or losses from operations, or other financial results, statements with respect to the plans, strategies and objectives of management for future operations, the potential for the Company's proprietary drug candidates, including fimepinostat, CA-4948, CA-170, the potential advantages and benefits of small molecule checkpoint antagonists, the Company's plans and expectations for the collaboration with Aurigene, including its plans to discover and develop multiple first-in-class oral, small molecule checkpoint antagonists for the treatment of patients with cancer, and the Company's plans to advance its development programs, including the timing of IND filings and the Company's plans for fimepinostat. Forward-looking statements may contain the words "believes," "expects," "anticipates," "plans," "intends," "seeks," "estimates," "assumes," "will," "may," "could" or similar expressions. These forward-looking statements are not guarantees of future performance and involve risks, uncertainties, assumptions and other important factors that may cause actual results to be materially different from those indicated by such forward-looking statements. For example, Curis may experience adverse results, delays and/or failures in its drug development programs and may not be able to successfully advance the development of its drug candidates in the time frames it projects, if at all. Curis's drug candidates may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical studies and/or may never achieve the requisite regulatory approvals needed for commercialization. Favorable results seen in preclinical studies and early clinical trials of Curis's drug candidates may not be replicated in later trials. There can be no guarantee that the collaboration agreement with Aurigene will continue for its full term, that Curis or Aurigene will each maintain the financial and other resources necessary to continue financing its portion of the research, development and commercialization costs, or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Regulatory authorities may determine to delay or restrict Genentech's and/or Roche's ability to continue to develop or commercialize Erivedge in BCC. Erivedge may not demonstrate sufficient or any activity to merit its further development in disease indications other than BCC. Competing drugs may be developed that are superior to Erivedge. In connection with its agreement with Oberland Capital, Curis faces risks relating to the transfer and encumbrance of certain royalty and royalty-related payments on commercial sales of Erivedge, including the risk that, in the event of a default by us or our wholly-owned subsidiary, we could lose all retained rights to future royalty and royalty-related payments, we could be required to repurchase such future royalty and royalty-related payments at a price that is a multiple of the payments we have received, and our ability to enter into future arrangements may be inhibited, all of which could have a material adverse effect on our business, financial condition and stock price. Curis will require substantial additional capital to fund its business and such capital may not be available on reasonable terms, or at all. Curis faces substantial competition. Curis also faces risks relating to potential adverse decisions made by the FDA and other regulatory authorities, investigational review boards, and publication review bodies. Curis may not obtain or maintain necessary patent protection and could become involved in expensive and time-consuming patent litigation and interference proceedings. Unstable market and economic conditions and unplanned expenses may adversely affect Curis's financial conditions and its ability to access the substantial additional capital needed to fund the growth of its business. Important factors that may cause or contribute to such differences include the factors set forth under the caption "Risk Factors" in our most recent Form 10-K and Form 10-Q and the factors that are discussed in other filings that we periodically make with the Securities and Exchange Commission ("SEC"). In addition, any forward-looking statements represent the views of Curis only as of today and should not be relied upon as representing Curis's views as of any subsequent date. Curis disclaims any intention or obligation to update any of the forward-looking statements after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by law.

CURIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)
(In thousands, except share and per share data)

	Three Months Ended June 30,		*Six Months Ended June 30,*	
	2019	***2018***	***2019***	***2018***
Revenues:				

Royalties	$ 2,142	$ 2,394	$ 4,279	$ 4,868
Contra revenue	(48)	(36)	(418)	(42)
Total revenues:	2,094	2,358	3,861	4,826
Operating expenses:				
Costs of royalty revenues	89	134	197	263
Research and development	5,620	6,451	9,694	14,717
General and administrative	2,526	3,633	5,669	7,614
Total operating expenses	8,235	10,218	15,560	22,594
Net loss from operations	(6,141)	(7,860)	(11,699)	(17,768)
Loss on debt extinguishment	—	—	(3,495)	—
Interest income	235	189	343	375
Non-cash imputed interest expense related to the sale of future royalty payments	(1,287)	—	(1,417)	—
Interest expense	(20)	(993)	(829)	(2,018)
Other expense, net	(1,072)	(804)	(5,398)	(1,643)
Net loss	(7,213)	(8,664)	(17,097)	(19,411)
Basic and diluted net loss per common share	$ (0.22)	$ (0.26)	$ (0.52)	$ (0.59)
Basic and diluted weighted average common shares outstanding	33,154,566	33,135,391	33,158,222	33,094,772

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	June 30, 2019	***December 31, 2018***
ASSETS		
Cash, cash equivalents and investments	$ 35,318	$ 24,270
Investments – restricted	153	153
Accounts receivable	2,134	2,864
Property and equipment, net	234	267
Operating lease right-of-use asset	598	—
Goodwill	8,982	8,982
Other assets	821	829
Total assets	$ 48,240	$ 37,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 3,736	$ 6,377
Operating lease liability	646	—
Debt obligations, net	—	35,484
Liability related to the sale of future royalties, net	64,127	—
Total liabilities	68,509	41,861
Total stockholders' equity	(20,269)	(4,496)
Total liabilities and stockholders' equity	$ 48,240	$ 37,365

SOURCE Curis, Inc.

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https://investors.curis.com/2019-08-06-Curis-Reports-Second-Quarter-2019-Financial-Results