Curis Reports Second Quarter 2018 Financial Results

-- Management to host conference call today at 8:30 a.m. EDT --

LEXINGTON, Mass., Aug. 2, 2018 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development and commercialization of innovative therapeutics for the treatment of cancer, today reported its financial results for the second quarter ended June 30, 2018.

"Our second quarter has been marked by continued progress in advancing our three clinical drug candidates further in their respective development," said Ali Fattaey, Ph.D., Chief Executive Officer of Curis. "We continue to assess and hold productive discussions with the FDA to identify a path to register fimepinostat, which could provide much-needed benefit for patients with R/R DLBCL, and in particular those whose disease have MYC alterations. CA-170, our orally available small-molecule checkpoint inhibitor, continues to progress in Phase 1 and Phase 2 clinical studies with a planned update in the second half of 2018. Patient enrollment continues for our recently initiated Phase 1 study of precision oncology candidate CA-4948, currently the only IRAK4 kinase inhibitor in clinical development for cancer. In addition, we recently welcomed Dr. Robert Martell into his new role as Head of Research and Development. Dr. Martell is a practicing oncologist whose extensive experience in drug development will help strengthen Curis's oncology portfolio. We believe Curis remains on track to advancing multiple attractive candidates with potential to substantially impact current oncology care."

Second Quarter 2018 Financial Results

Curis reported a net loss of $8.7 million, or $0.26 per share on both a basic and diluted basis for the second quarter of 2018, as compared to a net loss of $14.1 million, or $0.49 per share on both a basic and diluted basis for the same period in 2017. Curis reported a net loss of $19.4 million, or $0.59 per share, on both a basic and diluted basis for the six months ended June 30, 2018, as compared to a net loss of $29.8 million, or $1.04 per share on both a basic and diluted basis for the same period in 2017.

Revenues for the second quarter of 2018 were $2.4 million, as compared to $2.1 million for the same period in 2017. Revenues for the six months ended June 30, 2018 were $4.8 million, as compared to $4.2 million for the same period in 2017. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®.

Operating expenses were $10.2 million for the second quarter of 2018, as compared to $15.2 million for the same period in 2017. Operating expenses for the six months ended June 30, 2018 were $22.6 million, as compared to $32.4 million for the same period in 2017, and comprised the following:

Costs of Royalty Revenues. Costs of royalty revenues, resulting from payments to third-party university patent licensors associated with Genentech and Roche's Erivedge net sales, were $0.1 million for both the second quarter of 2018 and 2017. Cost of royalty revenues for the six months ended June 30, 2018 were $0.3 million, as compared to $0.2 million for the same period in 2017.

Research and Development Expenses. Research and development expenses were $6.5 million for the second quarter of 2018, as compared to $11.3 million for the same period in 2017. The decrease was primarily driven by decreased costs related to clinical activities for fimepinostat and CA-170, partially offset by increased costs related to CA-4948. Research and development expenses were $14.7 million for the six months ended June 30, 2018 as compared to $24.8 million for the same period in 2017.

General and Administrative Expenses. General and administrative expenses were $3.6 million for the second quarter of 2018 as compared to $3.8 million for the same period in 2017. The decrease in general and administrative expenses was primarily driven by lower personnel and stock-based compensation expense partially offset by higher legal services for the period. General and administrative expenses were $7.6 million for the six months ended June 30, 2018, as compared to $7.4 million for the same period in 2017.

Other Expenses. Net other expense for the second quarter 2018 totaled $0.8 million as compared to $1.0 million for the same period in 2017. Net other expense primarily consisted of interest expense related to Curis Royalty's (a wholly owned subsidiary of Curis) debt obligations. Other expense, net was $1.6 million and $1.7 million for the six months ended June 30, 2018 and 2017, respectively.

As of June 30, 2018, Curis's cash, cash equivalents, marketable securities and investments totaled $40.4 million and there were approximately 33.2 million shares of common stock outstanding.

Recent Operational Highlights

Precision oncology, fimepinostat (formerly CUDC-907):

Fimepinostat received Fast Track designation from the FDA for development in adult patients with relapsed or refractory DLBCL after two or more lines of systemic therapy.

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

Patient enrollment remained on track for the Phase 1 dose escalation trial evaluating CA-170 in patients with advanced solid tumors or lymphomas.
Curis collaborator Aurigene continued to enroll patients in a Phase 2 clinical study of CA-170 at select trial sites in India. Investigators have recently identified that mesothelioma tumor samples express high levels of VISTA immune checkpoint protein. We are extending our current Phase 1 trial to enroll a cohort of patients with mesothelioma.

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

Curis continued to enroll patients with relapsed or refractory non-Hodgkin lymphoma in a Phase 1 clinical trial evaluating CA-4948, a novel oral, small molecule IRAK4 kinase Inhibitor that has shown potent *in vivo* anti-tumor activity in preclinical animal models.
We have recently generated non-clinical data that demonstrate CA-4948 is active in *in vivo* models of AML. We are extending our current Phase 1 clinical trial to enroll a cohort of patients with AML.

Recent Corporate Highlights

Robert Martell, M.D., Ph.D., a practicing oncologist and experienced drug developer, was appointed Head of Research and Development and will directly manage the day-to-day operations of clinical development and research.
Curis announced a 1-for-5 reverse stock split reducing the number of Curis's outstanding common stock from approximately 165.6 million to approximately 33.1 million on March 29, 2018, the date of the reverse split.

Upcoming Activities

Curis anticipates providing an outline of the clinical development path for fimepinostat in 2H 2018.
Curis and collaborator Aurigene expect to provide additional updates in 2H 2018 on the clinical progress of CA-170, which is currently being evaluated in one Phase 1 and one Phase 2 study.
Curis expects to provide an update in 2H 2018 on the progress of CA-4948, which is currently being evaluated in a Phase 1 trial in patients with advanced lymphomas.

Conference Call Information

Curis management will host a conference call today, August 2, 2018, at 8:30 a.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 (United States) or 1-412-317-5252 (International), shortly before 8:30 a.m. EDT. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section. A replay of the call will be available on the Curis website shortly after the commencement of the meeting.

About Curis, Inc.

Curis is a biotechnology company focused on the development and commercialization 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 in the areas of immuno-oncology and precision oncology. As part of this collaboration, Curis has exclusive licenses to oral small molecule antagonists of immune checkpoints including, the PDL1/VISTA antagonist CA-170, and the PDL1/TIM3 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 advanced solid tumors and lymphomas, and in a Phase 2 trial 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.

Cautionary Note Regarding 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-170, and CA-4948, 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. Curis faces risks relating to its wholly-owned subsidiary's royalty-collateralized loan transaction, including the risk that it may not receive sufficient levels of royalty revenue from sales of Erivedge to satisfy the debt obligation or may otherwise lose its rights to royalties and royalty-related payments as a result of a foreclosure of the loan. 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,*	
	2018	*2017*	*2018*	*2017*
Revenues:				
Royalties	$ 2,394	$ 2,102	$ 4,868	$ 4,294
Research and development, net	(36)	(41)	(42)	(102)
Total revenues:	2,358	2,061	4,826	4,192
Operating expenses:				
Costs of royalty revenues	134	96	263	207
Research and development	6,451	11,255	14,717	24,795
General and administrative	3,633	3,819	7,614	7,351
Total operating expenses	10,218	15,170	22,594	32,353
Net loss from operations	(7,860)	(13,109)	(17,768)	(28,161)
Other (expense) income	—	—	—	(104)
Interest income	189	138	375	208
Interest expense	(993)	(1,119)	(2,018)	(1,775)

Other expense, net	(804)	(981)	(1,643)	(1,671)
Net loss	(8,664)	(14,090)	(19,411)	(29,832)
Basic and diluted net loss per common share	$ (0.26)	$ (0.49)	$ (0.59)	$ (1.04)
Basic and diluted weighted average common shares outstanding	33,135,391	28,757,341	33,094,772	28,580,828.8

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	June 30, 2018	*December 31, 2017*
ASSETS		
Cash, cash equivalents and investments	$ 40,420	$ 60,232
Investments – restricted	153	153
Accounts receivable	2,505	3,073
Property and equipment, net	352	366
Goodwill	8,982	8,982
Prepaid expense and other assets	779	992
Total assets	$ 53,191	$ 73,798
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 7,584	$ 8,250
Debt obligations, net	38,497	41,555
Total liabilities	46,081	49,805
Total stockholders' equity	7,110	23,993
Total liabilities and stockholders' equity	$ 53,191	$ 73,798

SOURCE Curis, Inc.

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