Curis Reports First Quarter 2020 Financial Results

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

LEXINGTON, Mass., May 12, 2020 /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 first quarter ended March 31, 2020.

"The first quarter of 2020 was productive for Curis, as we advanced our ongoing study for CA-4948 and accomplished several key licensing and financial objectives to support future progress across our pipeline and business," said James Dentzer, President and Chief Executive Officer of Curis. "In response to the COVID-19 pandemic, we have implemented both clinical and operational measures to help protect patients, staff, study investigators and our community, and I am incredibly proud of the resiliency and dedication our team continues to demonstrate during this difficult period. We look forward to updating efficacy data from our CA-4948 study in patients with non-Hodgkin's lymphoma (NHL) and remain on track to pursue clinical testing of CA-4948 in acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS), two areas of critical unmet need."

First Quarter 2020 and Recent Operational Highlights

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

Curis is evaluating its IRAK4 inhibitor, CA-4948 in an ongoing Phase 1 dose escalation study for the treatment of patients with relapsed or refractory (R/R) NHL, including patients with diffuse large B-cell lymphoma (DLBCL), Waldenström's macroglobulinemia (WM) and oncogenic MYD88 mutations. The Phase 1 study is on track and the Company expects to report updated efficacy data from the study and declare the recommended Phase 2 dose in 2020.

Due to the corona virus, certain sites for the Phase 1 study remain open for enrollment, while other sites have temporarily halted enrollment of new patients. Curis and its study investigators continue to monitor the COVID-19 pandemic and are focused on the safety and treatment of patients currently enrolled in the study.

Curis expects to initiate a separate Phase 1 trial of CA-4948 in patients with AML and MDS, including patients with spliceosome mutations that encode oncogenic IRAK4-L, in the second quarter of 2020.

Immuno-oncology, CI-8993 (anti-VISTA antibody; ImmuNext collaboration):

In January 2020, Curis announced it entered into an option and license agreement to acquire exclusive, worldwide rights from ImmuNext Inc. (ImmuNext) to develop and commercialize anti-VISTA antibodies for the treatment of cancer, including ImmuNext's lead clinical-stage compound, CI-8993. Ongoing non-clinical studies are underway, and the initial clinical study will begin in the second half of 2020.

Precision oncology, fimepinostat (HDAC/PI3K inhibitor):

Fimepinostat has previously been shown to induce durable single-agent responses in difficult-to-treat lymphomas, including MYC-driven and double-hit disease. Curis is collaborating with DarwinHealth on ongoing analytical research to characterize biomarkers and tumor subtype alignments, which may help guide future clinical development opportunities with fimepinostat.

COVID-19 and Business Operations:

Curis has implemented several clinical and operational measures to support the safety of patients, staff, and study investigators and maintain rigorous clinical trial conduct. Curis currently believes there will be no disruption to the clinical supply of CA-4948 or CI-8993. The Company is in close contact with its partners and manufacturers, and all parties have established procedures to manage drug supply during the COVID-19 pandemic.
Consistent with guidelines from the Centers for Disease Control (CDC) and the Commonwealth ofMassachusetts, Curis has implemented certain measures, such as ordering all employees to work remotely and restricting business travel, to help maintain the safety of its employees, families and community.

Upcoming 2020 Planned Milestones

Declare the recommended Phase 2 dose for CA-4948 in the ongoing lymphoma Phase 1 study and report updated efficacy data from the study.
Initiate a Phase 1 study of CA-4948 in patients with AML and MDS, including patients with spliceosome mutations that encode oncogenic IRAK4-L, in the second quarter of 2020.
Initiate a Phase 1a/1b dose escalation study of CI-8993 in in the second half of 2020.

First Quarter 2020 Financial Results

For the first quarter of 2020, Curis reported a net loss of $9.7 million, or $0.28 per share on both a basic and diluted basis, as compared to a net loss of $9.9 million, or $0.30 per share on both a basic and diluted basis for the same period in 2019.

Revenues for the first quarter of 2020 were $2.7 million, as compared to $1.8 million for the same period in 2019. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®.

Operating expenses for the first quarter of 2020 were $11.2 million, as compared to $7.3 million for the same period in 2019, 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 first quarter of 2020 and 2019.

Research and Development Expenses. Research and development expenses were $7.5 million for the first quarter of 2020, as compared to $4.1 million for the same period in 2019. The increase was primarily due to in-license expenses incurred from Curis' option and license agreement with ImmuNext, and increased costs related to clinical activities including consulting, outside lab expenses, and Contract Research Organization (CRO) services.

General and Administrative Expenses. General and administrative expenses were $3.6 million for the first quarter of 2020, as compared to $3.1 million for the same period in 2019. The increase was driven primarily by higher legal services during the period.

Other expense, net. Net other expense was $1.2 for the first quarter of 2020, as compared to $4.3 million for the same period in 2019. Net other expense for the first quarter 2020 primarily consisted of imputed interest expense related to future royalty payments, whereas in 2019 the expense related to the extinguishment of debt.

As of March 31, 2020, Curis' cash, cash equivalents, marketable securities and investments totaled $12.5 million and there were approximately 36.6 million shares of common stock outstanding. Curis expects that its existing cash, cash equivalents and investments should enable it to maintain its planned operations into the second half of 2020.

Conference Call Information

Curis management will host a conference call today, May 12, 2020, at 4:30 p.m. ET, 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. ET. 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. In 2015, Curis entered into 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 VISTA/PDL1 antagonist CA-170, and the TIM3/PDL1 antagonist CA-327, as well as the IRAK4 kinase inhibitor, CA-4948. CA-4948 is currently undergoing testing in a Phase 1 trial in patients with non-Hodgkin lymphoma. In addition, Curis is engaged in a collaboration with ImmuNext for development of CI-8993, a monoclonal anti-VISTA antibody. 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' 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 the Company's planned prioritization of resources, its plans to declare the recommended Phase 2 dose for CA-4948 in the ongoing lymphoma Phase 1 study and to report efficacy data from the trial in 2020, its plan to initiate a Phase 1 trial of 4948 in AML and MDS in the second quarter of 2020, its plans to initiate a Phase 1a/1b trial of CI-8993 in the second half of 2020, the impacts of the COVID-19 pandemic and the measures implemented in response thereto, the period in which Curis expects that its existing cash, cash equivalents and investments will enable it to fund its operations, its ability to access financing under its purchase agreement with Aspire or under its at-the-market sales agreement with JonesTrading, statements with respect to the plans, strategies and objectives of management for future operations, and the Company's expectations regarding the potential therapeutic benefit of its proprietary drug candidates. 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 agreements with Aurigene and ImmuNext will continue for their full terms, that Curis or its collaborators 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 Curis or its wholly-owned subsidiary, Curis could lose all retained rights to future royalty and royalty-related payments, Curis could be required to repurchase such future royalty and royalty-related payments at a price that is a multiple of the payments it has received, and its ability to enter into future arrangements may be inhibited, all of which could have a material adverse effect on its business, financial condition and stock price. Curis will require substantial additional capital to fund its business. Based on its available cash resources, it does not have sufficient cash on hand to support current operations within the next 12 months from the date of this press release. If it is not able to obtain sufficient funding, it will be forced to delay, reduce in scope or eliminate some of its research and development programs, including related clinical trials and operating expenses, potentially delaying the time to market for, or preventing the marketing of, any of its product candidates, which could adversely affect its business prospects and its ability to continue operations, and would have a negative impact on its financial condition and its ability to pursue its business strategies. If it is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on its audited financial statements, and it is likely that investors will lose all or a part of their investment. 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, natural disasters, public health crises, political crises and other events outside of Curis's control could significantly disrupt its operations or the operations of third parties on which Curis depends, and could adversely impact Curis's operating results and its ability to raise capital. For example, the COVID-19 pandemic may result in closures of third party facilities, impact enrollment in Curis's ongoing or planned clinical trials or impact sales of Erivedge by Genentech and/or Roche. The extent to which the COVID-19 pandemic may impact Curis's business or operating results is uncertain. Important factors that may cause or contribute to actual results being materially different from those indicated by forward-looking statements 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 March 31,	
	2020	***2019***
Revenues:		
Royalties	$ 2,515	$ 2,137
Other revenue	211	—
Contra revenue	(17)	(370)
Total revenues:	2,709	1,767
Operating expenses:		
Costs of royalty revenues	125	108
Research and development	7,473	4,074
General and administrative	3,593	3,143
Total operating expenses	11,191	7,325
Net loss from operations	(8,482)	(5,558)

Loss on debt extinguishment	—	(3,495)
Interest income	50	108
Imputed interest expense related to the sale of future royalty payments	(1,298)	(131)
Interest expense	—	(791)
Other income (expense), net	21	(17)
Total other expense, net	(1,227)	(4,326)
Net loss	(9,709)	(9,884)
Basic and diluted net loss per common share	$ (0.28)	$ (0.30)
Basic and diluted weighted average common shares outstanding	34,453,189	33,150,869

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	March 31, 2020	***December 31, 2019***
ASSETS		
Cash, cash equivalents and investments	$ 12,538	$ 20,543
Restricted cash	969	969
Accounts receivable	2,507	3,244
Property and equipment, net	396	154
Operating lease right-of-use asset	—	149
Goodwill	8,982	8,982
Other assets	1,314	1,066
Total assets	$ 26,706	$ 35,107
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Accounts payable, accrued liabilities and other liabilities	$ 5,986	$ 6,375
Operating lease liability	—	166
Liability related to the sale of future royalties, net	60,989	62,477
Total liabilities	66,975	69,018
Total stockholders' deficit	(40,269)	(33,911)
Total liabilities and stockholders' deficit	$ 26,706	$ 35,107

SOURCE Curis, Inc.

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