Curis Reports Third Quarter 2020 Financial Results

- Clinical data in CA-4948 NHL and AML/MDS trials to be presented in oral presentation and poster sessions at ASH -
- Patient Dosing initiated in Phase 1a/1b trial of anti-VISTA monoclonal antibody, CI-8993, in advanced refractory solid tumors -
- Initiation planned for Phase 1 trial of CA-4948 in combination with ibrutinib in NHL -
- Announced Cooperative Research and Development Agreement (CRADA) with National Cancer Institute (NCI) to collaborate on development of CA-4948 -
- Management to host conference call today at 4:30 p.m. ET -

LEXINGTON, Mass., Nov. 10, 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 third quarter ended September 30, 2020.

"We have continued to advance our clinical programs towards important catalysts at the end of this year and into 2021, which we expect to be another important year of data for Curis," said James Dentzer, President and Chief Executive Officer of Curis. "We have been pleased with the enrollment progress of our first-in-class IRAK4 inhibitor, CA-4948, in a Phase 1 study in patients with non-Hodgkin's lymphoma (NHL), and we look forward to providing an update at ASH. We began a second Phase 1 study for patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS) and we are pleased to announce today a CRADA with the NCI for further development of CA-4948 as an anti-cancer agent. We also look forward to initiating our Phase 1 combination study evaluating CA-4948 and the BTK inhibitor, ibrutinib, in patients with NHL, including those with MYD88 altered disease."

Mr. Dentzer continued, "We also initiated patient dosing during the third quarter in ourVISTA program, CI-8993, in the Phase 1a/1b study for patients with relapsed / refractory solid tumors. We are excited about our rapid progress from IND approval to patient dosing in this study and look forward to providing more updates over the coming quarters."

Third Quarter 2020 and Recent Operational Highlights

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

Curis is evaluating CA-4948 in an ongoing Phase 1 dose-escalation study for the treatment of patients with R/R NHL, including patients with diffuse large B-cell lymphoma (DLBCL), Waldenström's macroglobulinemia (WM) and oncogenic MYD88 mutations. An update of safety and efficacy data from the trial will be presented at the American Society of Hematology (ASH) Annual Meeting, which is being held virtually from December 5-8, 2020.
Curis continues to enroll patients in a second open-label Phase 1 dose-escalation study of CA-4948 in patients with R/R AML and high-risk MDS, including patients with spliceosome mutations that drive expression of the long isoform of IRAK4 (IRAK4-L). The primary objective of the study is to determine the maximum tolerated dose and recommended Phase 2 dose of CA-4948 based on safety and tolerability, dose-limiting toxicities (DLTs), and pharmacokinetic and pharmacodynamic findings. A minimum of three patients will be enrolled at each dose level, starting with 200 mg BID, which was determined to be safe, capable of achieving relevant levels of drug exposure, and demonstrated signs of biologic activity and clinical efficacy in a separate, ongoing Phase 1 study. Initial data from the study will be presented in a Trial in Progress poster at ASH.
Today, Curis announced that it entered into a CRADA with the NCI's Experimental Therapeutics Program for the development of CA-4948. Under the agreement, the NCI and Curis will collaborate on the non-clinical and clinical development of Curis's proprietary compound CA-4948, an IRAK-4 kinase inhibitor that acts as a Toll-like Receptor (TLR) suppressor as an anti-cancer agent.
Curis expects to initiate a Phase 1 study evaluating CA-4948 in combination with ibrutinib, a BTK inhibitor. In preclinical models, CA-4948 has demonstrated anti-cancer activity that is highly synergistic with BTK inhibition. The Company will present a Trial in Progress poster at ASH.

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

Curis initiated patient dosing in Q3 in a Phase 1a/1b study of CI-8993 in patients with relapsed / refractory solid tumors.
Curis will present a Trial in Progress poster on CI-8993 at the upcoming Society for Immunotherapy of Cancer's (SITC) 35th Anniversary Annual Meeting, which is being held virtually fromNovember 9-14, 2020.

Corporate:

As of November 3, 2020, extended cash runway through the second quarter of 2021, as a result of aggregate proceeds of approximately $10.0M since June 30, 2020 from the Company's at-the-market sales agreement with JonesTrading and stock purchase agreement with Aspire Capital.

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 later this quarter.
Report initial data later this quarter from the Phase 1 study of CA-4948 in patients with AML/MDS, including patients with spliceosome mutations that encode oncogenic IRAK4-L.
Continue enrollment in Phase 1a/1b dose escalation study of CI-8993 in patients with relapsed / refractory solid tumors.
Initiate Phase 1 study of CA-4948 in combination with ibrutinib.

Third Quarter 2020 Financial Results

For the third quarter of 2020, Curis reported a net loss of $6.0 million, or $0.11 per share on both a basic and diluted basis, as compared to a net loss of $6.4 million, or $0.19 per share on both a basic and diluted basis, for the same period in 2019. Curis reported a net loss of $22.4 million, or $0.52 per share on both a basic and diluted basis, for the nine months ended September 30, 2020 as compared to a net loss of $23.5 million, or $0.71 per share on both a basic and diluted basis for the same period in 2019.

Revenues for the third quarter of 2020 were $2.7 million, as compared to $2.9 million for the same period in 2019. Revenues for the nine months ended September 30, 2020 were $7.8 million, as compared to $6.7 million for the same period in 2019. Revenues for all periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®.

Operating expenses for the third quarter of 2020 were $7.5 million, as compared to $8.2 million for the same period in 2019. Operating expenses for the nine months ended September 30, 2020 were $26.4 million, as compared to $23.7 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 stable at $0.1 million for the third quarter of 2020, as compared to $0.1 million for the same period in 2019. Cost of royalty revenues for the nine months ended September 30, 2020 were $0.4 million, as compared to $0.3 million for the same period in 2019.

Research and Development Expenses. Research and development expenses were $4.7 million for the third quarter of 2020, as compared to $5.1 million for the same period in 2019. The decrease in research and development expenses for the quarter is primarily attributable to reduced clinical trial costs related to CA-170 and fimepinostat. Research and development expenses were $17.5 million for the nine months ended September 30, 2020, as compared to $14.8 million for the same period in 2019.

General and Administrative Expenses (G&A). General and administrative expenses were $2.6 million for the third quarter of 2020, as compared to $2.9 million for the same period in 2019. The decrease was driven primarily by lower personnel and stock-based compensation costs partially offset by higher legal, professional and consulting services costs. General and administrative expenses were $8.6 million for the nine months ended September 30, 2020, as compared to $8.6 million for the same period in 2019.

Other expense, net. Net other expense was $1.3 million for the third quarter of 2020, as compared to $1.1 million for the same period in 2019. Net other expense for the third quarter 2020 primarily consisted of imputed interest expense related to future royalty payments. Net other expense was $3.8 million for the nine months ended September 30, 2020, as compared to $6.5 million for the same period in 2019.

As of September 30, 2020, Curis' cash, cash equivalents, marketable securities and investments totaled $23.6 million and there were approximately 56.7 million shares of common stock outstanding. Curis expects that its existing cash, cash equivalents and investments should enable it to maintain its planned operations through the second quarter of 2021.

Conference Call Information

Curis management will host a conference call today, November 10, 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 and in a Phase 1 trial in patients with acute myeloid leukemia and myelodysplastic syndromes. In addition, Curis is engaged in a collaboration with ImmuNext for

development of CI-8993, a monoclonal anti-VISTA antibody, which is currently undergoing testing in a Phase 1a/1b trial in patients with solid tumors. 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 presentations and posters at upcoming conferences and expectations of data, the timing and reporting of potential data, catalysts and updates, its plans to declare the recommended Phase 2 dose for CA-4948 in the ongoing lymphoma Phase 1 study, its plans to initiate a combination study of CA-4948 with ibrutinib, the Company's plans to collaborate with the NCI on the development of CA-4948 under the CRADA, its plans for patient enrollment and dosing in the Phase 1a/1b trial of CI-8993, the impacts of the COVID-19 pandemic, 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues, net:				
Royalties	$ 2,720	$ 2,906	$ 7,681	$ 7,185
Other revenue	—	—	211	—
Contra revenue, net	22	(50)	(81)	(468)
Total revenues, net:	2,742	2,856	7,811	6,717
Operating expenses:				
Costs of royalty revenues	135	145	382	342
Research and development	4,705	5,147	17,459	14,840
General and administrative	2,613	2,887	8,593	8,557
Total costs and expenses	7,453	8,179	26,434	23,739
Loss from operations	(4,711)	(5,323)	(18,623)	(17,022)
Loss on debt extinguishment	—	—	—	(3,495)
Interest income	3	170	58	513
Imputed interest expense related to the sale of future royalties	(1,266)	(1,303)	(3,848)	(2,721)
Interest expense, debt	—	—	—	(791)
Other income (expense), net	—	20	22	(17)
Total other expense, net	(1,263)	(1,113)	(3,768)	(6,511)
Net loss	(5,974)	(6,436)	(22,391)	(23,533)
Basic and diluted net loss per common share	$ (0.11)	$ (0.19)	$ (0.52)	$ (0.71)
Basic and diluted weighted average common shares outstanding	54,554,129	33,202,871	42,884,201	33,170,844

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	September 30, 2020	December 31, 2019
ASSETS		
Cash, cash equivalents and investments	$ 23,555	$ 20,543
Restricted cash	816	969
Accounts receivable	2,744	3,244
Property and equipment, net	696	154
Operating lease right-of-use asset	6,915	149
Goodwill	8,982	8,982
Other assets	2,006	1,066
Total assets	$ 45,714	$ 35,107
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Accounts payable, accrued liabilities and other liabilities	$ 7,059	$ 6,375
Operating lease liability	7,036	166
Debt obligations	890	—
Liability related to the sale of future royalties, net	59,337	62,477
Total liabilities	74,322	69,018
Total stockholders' deficit	(28,608)	(33,911)

Total liabilities and stockholders' deficit	$ 45,714	$ 35,107

SOURCE Curis, Inc.

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