Curis Reports Third Quarter 2019 Financial Results

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

LEXINGTON, Mass., Nov. 5, 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 third quarter ended September 30, 2019.

"This past quarter, we made significant progress in advancing our clinical programs for fimepinostat and CA-4948, with continued enrollment across both Phase 1 trials and data readouts on-track for both programs in the fourth quarter of this year. We are particularly encouraged by the early indications of anti-cancer activity with CA-4948." said James Dentzer, President and Chief Executive Officer of Curis. "We are pleased by the safety and tolerability profile of CA-170 in our Phase 1 study and continue to believe VISTA is an important and scientifically-validated target. However, initial data suggest that CA-170 may not be an effective monotherapy agent for addressing VISTA in mesothelioma patients. We plan to further evaluate the translational science and clinical pharmacodynamics of CA-170, as well as the patient data from our Phase 1 study, to determine the optimal future clinical strategy for CA-170."

Third Quarter 2019 and Recent Operational Highlights

Precision oncology, fimepinostat (HDAC/PI3K inhibitor):

Curis is evaluating fimepinostat (a MYC suppressor) with venetoclax (a BCL-2 inhibitor) combination regimen in an ongoing Phase 1 study in diffuse large B-cell lymphoma (DLBCL), including patients with double-hit/double-expressor (DH/DE) lymphoma. DLBCL is often driven by specific alterations in both MYC and BCL2. In the clinic, fimepinostat and venetoclax have each demonstrated single-agent activity. 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):

Curis is evaluating CA-4948 in an ongoing Phase 1 dose escalation study in patients with non-Hodgkin lymphoma (NHL), including those with oncogenic MYD88 mutations and toll-like receptor (TLR) pathway activation. Curis plans to continue dose escalation in the study to determine the optimal dose for clinical development.
Curis plans to initiate a separate Phase 1 trial of CA-4948 in patients with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS), a focus on those with spliceosome mutations that encode oncogenic IRAK4-L.

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

Curis released initial efficacy data from its Phase 1 study of CA-170 in malignant plural mesothelioma (MPM) patients (high VISTA expressors) in conjunction with the Society for Immunotherapy of Cancer (SITC) 2019 Annual Meeting. The Phase 1 study was designed to evaluate the safety, recommended Phase 2 dose, and maximum tolerated dose of CA-170. Secondary endpoints included pharmacokinetic (PK) and anti-cancer activity, and exploratory endpoints included biomarkers and pharmacodynamic (PD) effects. The study enrolled 12 patients with MPM across 6 study sites within the U.S. and U.K., randomizing patients into two cohorts. The high-dose cohort received 1,200 mg twice-daily (BID) of CA-170, while the low-dose cohort received 200 mg BID of CA-170. Patients who did not respond or experienced disease progression at the 200 mg BID dose were crossed over to the high-dose cohort.

Of 12 patients enrolled, 11 patients have discontinued study treatment, with no partial or complete responses observed, per Response Evaluation Criteria In Solid Tumors (RECIST), Immune-related Response Criteria (irRC) or modified RECIST 1.1 for mesothelioma.
Of 11 patients on treatment for at least one post-baseline disease assessment, 7 had a best response of stable disease:

2 of 3 (66%) patients at the 200 mg BID dose (mean duration of 64 days)
5 of 8 (63%) patients assigned or escalated to the 1,200 mg BID dose (mean duration of 115 days)

CA-170 was generally safe and well-tolerated, with low rates of drug-related, immune-related or serious adverse events, and showed dose-proportional clinical PK.

Based on these data, Curis does not intend to enroll additional patients in this study. The Company plans to further evaluate the translational science and clinical pharmacodynamics of CA-170, in addition to patient data from the Phase 1 study, to assess the potential of future clinical studies of CA-170.
The Company is presenting the results from the Phase 1 study at the SITC 2019 Annual Meeting in National Harbor, Maryland:

Date/Time:	Saturday, November 9, 2019, 4:45 p.m. EST
Location:	Prince George's Exhibition Hall C
Poster Number:	O28

Title:	First-in-Class Small Molecule CA-170 Targeting VISTA: A Report on Efficacy Outcomes from a Cohort of 12 Malignant Pleural Mesothelioma (MPM) Patients in Study CA-170-101

Corporate:

In August 2019, Curis announced the appointments of Reinhard von Roemeling, M.D., as Senior Vice President, Clinical Development, and Christine Guertin as Vice President, Regulatory Affairs & Quality Assurance.
In September 2019, Curis announced the promotion of Bill Steinkrauss to Chief Financial Officer.

Upcoming 2019 Milestones

The company will be presenting at the 61st American Society of Hematology (ASH) Annual Meeting held December 7-10, 2019 in Orlando, FL, and will provide an update on:

Initial safety data from the Phase 1 study of the combination of fimepinostat and venetoclax in patients with R/R DLBCL, including patients with DH/DE lymphoma; and
Updated safety and efficacy data from the Phase 1 dose escalation study of CA-4948 in patients with NHL.

Third Quarter 2019 Financial Results

Curis reported a net loss of $6.4 million, or $0.19 per share on both a basic and diluted basis for the third quarter of 2019, as compared to a net loss of $7.2 million, or $0.22 per share on both a basic and diluted basis for the same period in 2018.

Revenues for the third quarter of 2019 were $2.9 million, as compared to $2.8 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 third quarter of 2019, as compared to $9.3 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 the third quarter of 2019, as compared to $0.2 million for the same period in 2018.

Research and Development Expenses (R&D). R&D expenses were $5.1 million for the third quarter of 2019, as compared to $5.0 million for the same period in 2018. The increase was primarily driven by increased costs related to clinical activities for CA-4948.

General and Administrative Expenses (G&A). G&A expenses were $2.9 million for the third quarter of 2019 as compared to $4.1 million for the same period in 2018. The decrease was primarily driven by lower personnel, legal and consulting services during the period.

Other Expenses. Net other expense for the third quarter 2019 was $1.1 million, as compared to $0.8 million for the same period in 2018. Net other expense for the third quarter 2019 primarily consisted of imputed interest expense related to future royalty payments, whereas in 2018 the expense related to interest accrued on Curis Royalty's debt obligations.

As of September 30, 2019, Curis's cash, cash equivalents, marketable securities and investments totaled $28.0 million and there were approximately 33.2 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, November 5, 2019, at 8:30 a.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 8:30 a.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, 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 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. 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, the period in which Curis expects that its existing cash, cash equivalents and investments will enable it to fund its operations, 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 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 and such capital may not be available on reasonable terms, or at all. Without sufficient additional funding, Curis will not be able to continue as a going concern and may be forced to delay, reduce in scope or eliminate some of its research and development programs, which could adversely affect its business prospects and its ability to continue operations. Substantial doubt about Curis's ability to continue as a going concern may adversely affect Curis's ability to access the substantial additional capital needed to continue operations. 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 September 30,		***Nine Months Ended September 30,***	
	2019	***2018***	***2019***	***2018***
Revenues:				
Royalties	$ 2,906	$ 2,781	$ 7,185	$ 7,649
Contra revenue	(50)	66	(468)	24
Total revenues:	2,856	2,847	6,717	7,673
Operating expenses:				
Costs of royalty revenues	145	154	342	417
Research and development	5,147	4,983	14,840	19,700

General and administrative	2,887	4,127	8,557	11,741
Total operating expenses	8,179	9,264	23,739	31,858
Net loss from operations	(5,323)	(6,417)	(17,022)	(24,185)
Loss on debt extinguishment	—	—	(3,495)	—
Interest income	170	166	513	541
Imputed interest expense related to the sale of future royalties	(1,303)	—	(2,721)	—
Interest expense, debt	—	(972)	(791)	(2,990)
Other income (expense), net	20	—	(17)	—
Other expense, net	(1,113)	(806)	(6,511)	(2,449)
Net loss	(6,436)	(7,223)	(23,533)	(26,634)
Basic and diluted net loss per common share	$ (0.19)	$ (0.22)	$ (0.71)	$ (0.80)
Basic and diluted weighted average common shares outstanding	33,202,871	33,161,592	33,170,844	33,117,290

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	September 30, 2019	***December 31, 2018***
ASSETS		
Cash, cash equivalents and investments	$ 28,009	$ 24,270
Investments – restricted	153	153
Accounts receivable	2,897	2,864
Property and equipment, net	203	267
Operating lease right-of-use asset	373	—
Goodwill	8,982	8,982
Other Assets	1,627	829
Total assets	$ 42,244	$ 37,365
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Accounts payable, accrued liabilities and other liabilities	$ 4,309	$ 6,377
Operating lease liability	409	—
Debt obligations, net	—	35,484
Liability related to the sale of future royalties, net	63,544	—
Total liabilities	68,262	41,861
Total stockholders' deficit	(26,018)	(4,496)
Total liabilities and stockholders' deficit	$ 42,244	$ 37,365

SOURCE Curis, Inc.

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