Curis Reports First Quarter 2019 Financial Results

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

LEXINGTON, Mass., May 14, 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 first quarter ended March 31, 2019.

"2019 has been a transformational year for Curis as we demonstrate the results of our heightened focus on clinical execution. We are currently on track or ahead of schedule in the execution of all three of our clinical trials," said James Dentzer, President and Chief Executive Officer of Curis. "We look forward to discussing clinical data from all three trials later this year: this summer for CA-4948 and later in the second half for fimepinostat and CA-170."

"Furthermore, with this quarter's agreement with Oberland Capital, for $65 million upfront and up to $70.7 million in additional milestones, we secured the financial flexibility needed to ensure we can continue to move forward aggressively in our clinical execution of all three programs," he concluded.

First Quarter 2019 Financial Results

Curis reported a net loss of $9.9 million, or $0.30 per share on both a basic and diluted basis for the first quarter of 2019, as compared to a net loss of $10.7 million, or $0.33 per share on both a basic and diluted basis for the same period in 2018.

Revenues for the first quarter of 2019 were $1.8 million, as compared to $2.5 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 $7.3 million for the first quarter of 2019, as compared to $12.4 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 first quarter of 2019 and 2018.

Research and Development Expenses. Research and development expenses were $4.1 million for the first quarter of 2019 as compared to $8.3 million for the same period in 2018. The decrease was primarily due to decreased costs related to ongoing clinical and manufacturing activities for fimepinostat and CA-170. Employee-related expenses decreased from the prior quarter primarily due to a reduction in headcount that occurred in the fourth quarter of 2018. These changes reflect our shift in focus toward clinical development, while down-sizing the in-house discovery research organization. We have also focused the CA-170 program toward the VISTA-expressing mesothelioma indication, which allowed substantial reduction in the number of sites and regions required.

General and Administrative Expenses. General and administrative expenses were $3.1 million for the first quarter of 2019 as compared to $4.0 million for the same period in 2018. The decrease in general and administrative expenses was driven primarily by lower personnel, legal, and stock-based compensation for the period.

Other expense, net was $4.3 million for the first quarter of 2019, as compared to $0.8 million for the same period in 2018. Other expense, net primarily consisted of the loss on extinguishment of $3.5 million and interest expense of $0.8 million related to Curis Royalty's (a wholly owned subsidiary of Curis) debt obligations.

As of March 31, 2019, Curis's cash, cash equivalents and investments totaled $42.8 million and there were approximately 33.2 million shares of common stock outstanding.

Recent Operational Highlights

Precision oncology, fimepinostat (HDAC/PI3K inhibitor):

> Curis is initiating a 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 Lymphoma. 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):

> In April 2019, Curis advanced to the 200mg BID cohort in the CA-4948 study for treatment of patients with

non-Hodgkin lymphoma, including those with MYD88 alterations.

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

In January 2019, Curis dosed the first mesothelioma patient in its ongoing Phase 1 CA-170 trial following evidence supporting high levels of VISTA expression in mesothelioma tumor samples. Recent publications have identified VISTA as a possible resistance mechanism to treatment with anti-PD1 antibodies in several cancer indications.

In May 2019, Curis announced completion of its target enrollment of mesothelioma patients in the ongoing Phase 1 CA-170 trial.

First Quarter 2019 and Recent Corporate Highlights

In March 2019, Curis announced that it sold a portion of its Erivedge royalties to Oberland Capital for up to $135.7 million, including $65 million upfront.

2019 Data Catalysts

For the remainder of the year, Curis expects to:

Report initial data on the combination of fimepinostat and venetoclax regimen in patients with R/R DLBCL, including patients with DH/DE Lymphoma, in the second half of 2019.

Report initial efficacy data from its CA-4948 dose escalation study in patients with NHL in mid-year 2019.

Report initial efficacy data from its CA-170 Phase 1 trial in patients with mesothelioma (high VISTA expressors) in the second half of 2019.

Conference Call Information

Curis management will host a conference call today, May 14, 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.

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-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 March 31,	
	2019	*2018*
Revenues:		
Royalties	$ 2,137	$ 2,474
Contra revenue	(370)	(6)
Total revenues:	1,767	2,468
Operating expenses:		
Costs of royalty revenues	108	129
Research and development	4,074	8,266
General and administrative	3,143	3,981
Total operating expenses	7,325	12,376
Net loss from operations	(5,558)	(9,908)
Loss on debt extinguishment	(3,495)	—
Interest income	108	186
Non-cash imputed interest expense related to the sale of future royalty payments	(131)	—
Interest expense	(808)	(1,025)
Total other expense, net	(4,326)	(839)
Net loss	(9,884)	(10,747)
Basic and diluted net loss per common share	$ (0.30)	$ (0.33)
Basic and diluted weighted average common shares outstanding	33,150,869	33,053,702

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	March 31, 2019	*December 31, 2018*
ASSETS		
Cash, cash equivalents and investments	$ 42,796	$ 24,270
Investment – restricted	153	153
Accounts receivable	1,786	2,864
Property and equipment, net	226	267
Operating lease right of-use asset	822	—
Goodwill	8,982	8,982
Other assets	684	829
Total assets	$ 55,449	$ 37,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 3,753	$ 6,377
Operating lease liability	878	—
Debt obligations, net	—	35,484
Liability related to the sale of future royalties, net	64,547	—
Total liabilities	69,178	41,861
Total stockholders' equity	(13,729)	(4,496)
Total liabilities and stockholders' equity	$ 55,449	$ 37,365

SOURCE Curis, Inc.

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