Curis Reports Fourth Quarter and Year-End 2018 Financial Results

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

LEXINGTON, Mass., March 26, 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 fourth quarter and year ended December 31, 2018.

"2018 was a pivotal year for Curis as we transitioned from a company broadly engaged in discovery research and pipeline expansion into a company singularly focused on clinical execution," said James Dentzer, President and Chief Executive Officer of Curis. "We now have three novel programs in the clinic, all potential blockbusters and all with significant data catalysts expected in 2019."

Dentzer continued, "With our recently announced agreement with Oberland Capital, we secured the financial flexibility needed to ensure we can continue to move forward aggressively in our clinical execution on all three programs and produce the data readouts everyone is so excited to see.

"As we move through 2019, we are focused on the development of first-in-class and best-in-class precision medicines that we hope will transform the lives of patients," he concluded.

Full Year and Fourth Quarter 2018 Financial Results

For the year ended December 31, 2018, Curis reported a net loss of $32.6 million, or $0.98 per share on both a basic and diluted basis, as compared to a net loss of $53.3 million, or $1.79 per share on both a basic and diluted basis in 2017. For the fourth quarter of 2018, Curis reported a net loss of $5.9 million or $0.18 per share on both a basic and diluted basis, as compared to a net loss of $8.0 million, or $0.24 per share on both a basic and diluted basis for the same period in 2017.

Revenues for the year ended December 31, 2018, were $10.4 million as compared to $9.9 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®. Revenues for the fourth quarters of 2018 and 2017 were $2.8 million and $3.3 million, respectively.

Operating expenses for the year ended December 31, 2018 were $39.8 million as compared to $59.7 million for the same period in 2017. Operating expenses for the fourth quarter of 2018 were $7.9 million, as compared to $10.4 million for the same period in 2017, 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 $0.6 million for the year ended December 31, 2018 as compared to $0.5 million for the same period in 2017. Cost of royalty revenues were $0.1 million for the fourth quarter of 2018, as compared to $0.2 million for the same period in 2017.

Research and Development Expenses. Research and development expenses were $24.4 million for the year ended December 31, 2018, as compared to $45.1 million for the same period in 2017. The decrease was primarily due to aggregate payments to Aurigene of $7.5 million, for an exclusivity option that was paid in 2017 as well as decreased costs related to ongoing clinical activities for CA-170. These costs included decreased clinical site, patient, clinical research organization, formulation and manufacturing and consulting costs for our ongoing Phase 1 clinical trial. Employee-related expenses decreased over the prior year period primarily due to a reduction in headcount that occurred in the fourth quarter of 2018. Research and development expenses were $4.7 million for the fourth quarter of 2018 as compared to $6.9 million for the same period in 2017.

General and Administrative Expenses. General and administrative expenses were $14.8 million for the year ended December 31, 2018 as compared to $14.1 million for the same period in 2017. The increase in general and administrative expenses was driven primarily by higher legal, professional and consulting services and other administrative expenses, partially offset by lower stock-based compensation for the period. General and administrative expenses were $3.0 million for the fourth quarter of 2018, as compared to $3.3 million for the same period in prior 2017.

Other expense, net, was $3.2 million for the year ended December 31, 2018, as compared to $3.6 million for the same period in 2017. Other expense, net primarily consisted of interest expense related to the debt obligations of Curis Royalty (a wholly owned subsidiary of Curis). The decrease in interest expense in the current year was related to a lower principal balance on Curis Royalty's outstanding debt with HealthCare Royalty, which was refinanced in the first quarter of 2017. Other expense, net was $0.8 million and $0.9 million for the fourth quarter of 2018 and 2017, respectively.

As of December 31, 2018, Curis' cash, cash equivalents, marketable securities and investments totaled $24.3 million and there were approximately 33.2 million shares of common stock outstanding. The previously announced sale of a portion of Erivedge royalties to Oberland Capital Management will provide net proceeds of approximately $30 million before closing costs and

transaction fees.

Full Year 2018 and Recent Operational Highlights

Precision oncology, fimepinostat (HDAC/PI3K inhibitor):

- Curis initiated its study of fimepinostat (a MYC inhibitor) 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.
- In December 2018 at the American Society of Hematology's (ASH) annual meeting, Curis presented a pooled analysis of patients with relapsed/refractory DLBCL treated with fimepinostat, including individuals with MYC-alterations that demonstrated the treatment's safety and durable benefit in this patient population.

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

- In 2018, Curis initiated and continued to enroll patients with relapsed or refractory non-Hodgkin lymphoma in a Phase 1 dose escalation study. CA-4948 is designed to target cancers with MYD88 mutations present in various tumor cell lines including DLBCL, Waldenström's macroglobulinemia (WM), and acute myeloid leukemia.
- In December 2018, at the ASH annual meeting, Curis presented preclinical results showing potent anti-tumor *in vivo* activity for CA-4948 as a single agent as well as an enhanced effect when combined with other agents supporting the potential for IRAK4-based combination regimens.

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

- In November 2018, at the Society for Immunotherapy of Cancer's Annual Meeting, Curis presented three posters providing an update to the ongoing CA-170 Phase 1 trial and preclinical support of VISTA's role as an oncology target of interest. At the same conference, collaborator Aurigene presented a poster detailing key findings from its ongoing Phase 2 trial of CA-170 in patients with advanced solid tumors and Hodgkin lymphoma who are immunotherapy treatment-naïve.
- In January 2019, Curis announced the first mesothelioma patient dosed in its ongoing Phase 1 CA-170 trial, which recently started to enroll patients with mesothelioma, 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.

Full Year 2018 and Recent Corporate Highlights

- Curis announced a 1-for-5 reverse stock split that came into effect on May 29, 2018.
- In May 2018, Curis appointed Robert Martell, M.D., Ph.D., a practicing oncologist, experienced drug developer and former CMO of Tesaro, as Head of Research and Development.
- In September 2018, Curis announced the appointment of James Dentzer to the position of President and Chief Executive Officer.
- In October 2018, Curis implemented a 27% reduction in headcount and a re-allocation of pre-clinical resources to strengthen focus on clinical development. The result of these changes reduced the forecasted cash burn from approximately $11 million to $8 million per quarter going forward.
- 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 and $70.7 million in future milestones.

2019 Data Catalysts

- 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.
- Curis expects to report initial efficacy data from its CA-4948 dose escalation study in patients with D/DE DLBCL in mid-year 2019.
- Curis expects to 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, March 26, 2019, 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 in the Investors section on the Curis website at www.curis.com.

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 advanced solid tumors, lymphomas, and mesothelioma 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' 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' 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' 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' 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' 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	*Year ended*
December 31,	*December 31,*

	2018	2017	2018	2017
Revenues:				
Royalties	$ 2,772	$ 3,144	$ 10,421	$ 9,849
Research and development, net	(17)	118	7	49
Total revenues:	2,755	3,262	10,428	9,898
Operating expenses:				
Costs of royalty revenues	146	165	563	496
Research and development	4,713	6,918	24,413	45,096
General and administrative	3,044	3,306	14,785	14,066
Total operating expenses	7,903	10,389	39,761	59,658
Net loss from operations	(5,148)	(7,127)	(29,333)	(49,760)
Other (expense) income	—	(1)	—	(104)
Interest income	143	182	684	513
Interest expense	(936)	(1,082)	(3,926)	(3,966)
Other expense, net	(793)	(901)	(3,242)	(3,557)
Net loss	(5,941)	(8,028)	(32,575)	(53,317)
Basic and diluted net loss per common share	$ (0.18)	$ (0.24)	$ (0.98)	$ (1.79)
Basic and diluted weighted average common shares outstanding	33,121,666	32,801,650	33,118,393	29,826,693

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	December 31, 2018	December 31, 2017
ASSETS		
Cash, cash equivalents and investments	$ 24,270	$ 60,232
Investments – restricted	153	153
Accounts receivable	2,864	3,073
Property and equipment, net	267	366
Goodwill	8,982	8,982
Other assets	829	992
Total assets	$ 37,365	$ 73,798
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 6,377	$ 8,250
Debt obligations, net	35,484	41,555
Total liabilities	41,861	49,805
Total stockholders' equity	(4,496)	23,993
Total liabilities and stockholders' equity	$ 37,365	$ 73,798

SOURCE Curis, Inc.

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https://investors.curis.com/2019-03-26-Curis-Reports-Fourth-Quarter-and-Year-End-2018-Financial-Results