Curis Reports Third Quarter 2018 Financial Results

-- New leadership increasing focus on clinical execution --
-- Management to host conference call today at 8:30 a.m. EDT --

LEXINGTON, Mass., Nov. 1, 2018 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today reported financial results for the third quarter ended September 30, 2018.

"Following Curis's recent leadership change, we are increasing our focus on the clinical execution of our three first-in-class therapeutics that have the potential to be significant and innovative cancer treatments. We expect all three drug candidates to progress rapidly in the clinic and have data readouts in 2019," said James Dentzer, President & Chief Executive Officer of Curis. "To achieve this goal, we are re-allocating resources to prioritize clinical operations and have implemented a reduction in headcount and expenditure on pre-clinical science, pipeline expansion, and general and administrative expenses. We expect these reductions will offset an increase in headcount and costs associated with clinical operations and result in net savings for the Company, reducing cash burn from approximately $11 million to $8 million per quarter. This renewed focus on clinical execution will benefit patients in need of life-changing medications and shareholders alike," Mr. Dentzer concluded.

Third Quarter 2018 Financial Results

Curis reported a net loss of $7.2 million, or $0.22 per share on a basic and diluted basis for the third quarter of 2018, as compared to a net loss of $15.5 million, or $0.53 per share respectively for the same period in 2017.

Revenues for the third quarter of 2018 were $2.8 million, as compared to $2.4 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®.

Operating expenses were $9.3 million for the third quarter of 2018, as compared to $16.9 million for the same period in 2017, and comprised the following:

Costs of Royalty Revenues. Costs of royalty revenues, resulting from payments to third-party university patent licensors associated with Genentech and Roche's Erivedge net sales, were $0.2 million as compared to $0.1 million for the same period in 2017.

Research and Development Expenses. Research and development expenses were $5.0 million, as compared to $13.4 million for the same period in 2017. The decrease was primarily driven by decreased costs related to clinical activities and manufacturing for fimepinostat, CA-170 and CA-4948 and a payment to Aurigene of $3.8 million for an exclusivity option in September 2017.

General and Administrative Expenses. General and administrative expenses were $4.1 million as compared to $3.4 million for the same period in 2017. The increase in general and administrative expenses was primarily driven by higher personnel costs and professional and consulting services partially offset by lower stock-based compensation for the period.

Other Expenses. Net other expenses totaled $0.8 million as compared to $1.0 million for the same period in 2017. Net other expense primarily consisted of interest expense related to Curis Royalty's (a wholly owned subsidiary of Curis) debt obligations.

As of September 30, 2018, Curis's cash, cash equivalents and investments totaled $30.8 million and there were approximately 33.1 million shares of common stock outstanding.

Recent Operational Highlights

Precision oncology, fimepinostat (formerly CUDC-907):

Having received Fast Track designation for fimepinostat, Curis is working with the FDA and select clinical sites to initiate a combination study of fimepinostat (a MYC inhibitor) with venetoclax (a BCL-2 inhibitor) in DLBCL, including patients with DH/DE Lymphoma.

DLBCL with alterations in both the MYC gene and the BCL2 gene is defined as Double-Hit Lymphoma. In preclinical studies, the combination of fimepinostat with venetoclax has demonstrated highly synergistic effect, resulting in significant tumor size reduction.

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

Curis continues to enroll patients with relapsed or refractory non-Hodgkin lymphoma in a dose escalation study evaluating CA-4948, a first-in-class oral, small molecule IRAK4 kinase inhibitor. CA-4948 is designed to target cancers with MYD88 mutations in DLBCL and Waldenström's macroglobulinemia.

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

Patient treatment continues in the dose escalation study evaluating CA-170 in patients with advanced solid tumors or lymphomas.

Curis is working with select clinical sites to initiate a study of CA-170 in patients with mesothelioma, following evidence of mesothelioma tumor samples expressing high levels of VISTA. Recent publications have identified VISTA as a possible resistance mechanism to treatment with anti-PD1 antibodies in several cancer indications.

Curis collaborator Aurigene continues to enroll immunotherapy treatment-naïve patients in a clinical study of CA-170 at select trial sites in India.

Recent Corporate Highlights

In September, Curis announced change in leadership with the appointment of James Dentzer to the position of President and Chief Executive Officer.

In October, Curis implemented a 27% reduction in headcount and a re-allocation of pre-clinical resources to strengthen focus on clinical development. The Company expects the net result of expense reductions in pre-clinical R&D and G&A and targeted increases in clinical operations to result in a total cash burn reduction from approximately $11 million to $8 million per quarter going forward.

Upcoming Activities

Curis will provide an update on the dose escalation study of CA-170 at the annual SITC conference in November.

2019 Data Catalysts

Curis expects to commence enrollment in a combination study evaluating a fimepinostat and venetoclax regimen in patients with R/R DLBCL, including patients with DH/DE Lymphoma, in the first half of 2019 and report initial data in the second half of 2019.

Curis expects to report initial data from an ongoing dose escalation study evaluating CA-4948 in patients with R/R DLBCL and WM, including patients with MYD88-altered disease, by mid-year 2019.

Curis expects to commence enrollment in a clinical study evaluating CA-170 in patients with mesothelioma (high VISTA expressors) in the first half of 2019 and report initial data in the second half of 2019.

Conference Call Information

Curis management will host a conference call today, November 1, 2018, 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 (United States) or 1-412-317-5252 (International), 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. A replay of the call will be available on the Curis website shortly after the commencement of the meeting.

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-170 is currently undergoing testing in a Phase 1 trial in patients with advanced solid tumors and lymphomas, 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'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 CUDC-907. 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. 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'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,*	
	2018	*2017*	*2018*	*2017*
Revenues:				
Royalties	$ 2,781	$ 2,412	$ 7,649	$ 6,706
Research and development, net	66	32	24	(70)
Total revenues:	2,847	2,444	7,673	6,636

Operating expenses:				
Costs of royalty revenues	154	124	417	331
Research and development	4,983	13,382	19,700	38,177
General and administrative	4,127	3,409	11,741	10,760
Total operating expenses	9,264	16,915	31,858	49,268
Net loss from operations	(6,417)	(14,471)	(24,185)	(42,632)
Other (expense) income	—	—	—	(104)
Interest income	166	123	541	331
Interest expense	(972)	(1,109)	(2,990)	(2,884)
Other expense, net	(806)	(986)	(2,449)	(2,657)
Net loss	(7,223)	(15,457)	(26,634)	(45,289)
Basic and diluted net loss per common share	$ (0.22)	$ (0.53)	$ (0.80)	$ (1.57)
Basic and diluted weighted average common shares outstanding	33,161,592	29,302,839	33,117,290	28,824,143

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	September 30, 2018	*December 31, 2017*
ASSETS		
Cash, cash equivalents and investments	$ 30,833	$ 60,232
Investments – restricted	153	153
Accounts receivable	2,855	3,073
Property and equipment, net	312	366
Goodwill	8,982	8,982
Prepaid expense and other assets	1,130	992
Total assets	$ 44,265	$ 73,798
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 6,337	$ 8,250
Debt obligations, net	37,146	41,555
Total liabilities	43,483	49,805
Total stockholders' equity	782	23,993
Total liabilities and stockholders' equity	$ 44,265	$ 73,798

SOURCE Curis, Inc.

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https://investors.curis.com/2018-11-01-Curis-Reports-Third-Quarter-2018-Financial-Results