Curis Reports Fourth Quarter and Year-End 2017 Financial Results

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

LEXINGTON, Mass., March 8, 2018 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development and commercialization of innovative and effective therapeutics for the treatment of cancer, today reported its financial results for the fourth quarter and year ended December 31, 2017.

"2017 exemplified Curis's business strategy, marking the Company's first time with three anti-cancer drug candidates in clinical development" said Ali Fattaey, Ph.D., Chief Executive Officer of Curis. "We are excited about CUDC-907 treatment providing durable responses in nearly 1 in 4 DLBCL patients whose cancers have MYC alterations. We are working closely with regulatory authorities to define a pivotal path to register CUDC-907 in this patient population, which has no viable treatment options."

"Our progress with testing CA-170, the first and only oral small molecule checkpoint inhibitor, has now extended beyond the Phase 1 trial, with our partner Aurigene having initiated a Phase 2 trial in India. This will greatly accelerate access to select populations of patients that have not experienced prior immunotherapy."

"As noted, with initiation of patient enrollment in CA-4948's Phase 1 lymphoma study, for the first time, Curis has 3 different cancer drugs in clinical testing at the same time. We are excited about the prospects for these drugs and their value to Curis's success in 2018."

Full Year and Fourth Quarter 2017 Financial Results

For the year ended December 31, 2017, Curis reported a net loss of $53.3 million, or $(0.36) per share on both a basic and diluted basis, as compared to a net loss of $60.4 million, or $(0.45) per share on both a basic and diluted basis in 2016. For the fourth quarter of 2017, Curis reported a net loss of $8.0 million or $(0.05) per share on both basic and diluted basis, as compared to a net loss of $11.3 million, or $(0.08) per share on both basic and diluted basis for the same period in 2016. The net loss for the year ended December 31, 2016, includes a non-cash in-process research and development charge of $18.0 million related to the amendment of Curis's license agreement with Aurigene.

Revenues for the year ended December 31, 2017 were $9.9 million, as compared to $7.5 million for the same period in 2016. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®. Revenues for the fourth quarters of 2017 and 2016 were $3.3 million and $2.4 million, respectively.

Operating expenses were $59.7 million for the year ended December 31, 2017, as compared to $65.6 million for the same period in 2016. Operating expenses for the fourth quarter of 2017 were $10.4 million, as compared to $13.1 million for the same period in 2016, 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 $0.5 million for the year ended December 31, 2017, as compared to $0.4 million for the same period in 2016. Cost of royalty revenues were $0.2 million for the fourth quarter of 2017, as compared to $0.1 million for the same period in 2016.

In-Process Research and Development Expense. The Company recorded a one-time in-process research and development expense of $18.0 million for the year ended December 31, 2016, related to the issuance of common stock to Aurigene. These shares were issued as consideration for the rights granted under the terms of the September 2016 amendment to the collaboration agreement.

Research and Development Expenses. Research and development expenses were $45.1 million for the year ended December 31, 2017, as compared to $31.6 million for the same period in 2016. The increase was primarily due to two payments to Aurigene for $3.8 million each, for an exclusivity option which were paid in January 2017 and September 2017 as well as increased costs related to ongoing clinical activities for CA-170. Employee-related expenses increased over the prior year period primarily due to higher stock based compensation and personnel costs. Research and development expenses were $6.9 million for the fourth quarter of 2017, as compared to $9.2 million for the same period in 2016.

General and Administrative Expenses. General and administrative expenses were $14.1 million for the year ended December 31, 2017, as compared to $15.6 million for the same period in 2016. The decrease in general and administrative expenses was driven primarily by lower legal, professional and consulting services and other administrative expenses, offset slightly by higher stock-based compensation for the period. General and administrative expenses were $3.3 million for the fourth quarter of 2017, as compared to $3.8 million for the same period in 2016.

Other expense, net was $3.6 million for the year ended December 31, 2017, as compared to $2.4 million for the same period in 2016. Other expense, net primarily consisted of interest expense related to the debt obligations of Curis Royalty (a wholly owned subsidiary of Curis). The increase in interest expense in the current year was related to a higher principal balance of Curis Royalty's outstanding debt with HealthCare Royalty, which was refinanced in the first quarter of 2017. Other expense, net was $0.9 million for the fourth quarter of 2017, as compared to $0.6 million for the same period in 2016.

As of December 31, 2017, Curis's cash, cash equivalents, marketable securities and investments totaled $60.2 million and there were approximately 164.2 million shares of common stock outstanding.

Recent Operational Highlights

Precision oncology, CUDC-907:

In December 2017, investigators presented results from the combined analysis of the Phase 1 and Phase 2 trial results of CUDC-907 in patients with relapsed/refractory DLBLC, including those with MYC-altered disease, at the American Society of Hematology's annual meeting in Atlanta, Georgia.

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

In December 2017, Curis scientists presented non-clinical results demonstrating significant anti-tumor activity when CA-4948 was combined with the BCL2 antagonist drug venetoclax, at the American Society of Hematology's annual meeting in Atlanta, Georgia. In January 2018, Curis announced initiation of patient dosing in a Phase 1 trial of CA-4948 for treatment of patients with lymphoma. CA-4948 was discovered at Aurigene and is the second licensed program from the Curis-Aurigene collaboration to enter the clinic.

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

In November 2017, investigators presented preliminary results from the dose escalation stage of the Phase 1 trial of CA-170 in patients with advanced solid tumors or lymphomas, at the annual meeting of the Society for Immunotherapy of Cancer, in National Harbor, Maryland.
Curis collaborator, Aurigene, initiated patient enrollment of cancer patients in a Phase 2 clinical study of CA-170 at trial sites in India.

Immuno-oncology, CA-327 (PDL1 and TIM3 antagonist; Aurigene collaboration):

In November 2017, Curis scientists presented non-clinical results demonstrating CA-327's ability to modulate tumor immune profile in mouse models, as well as its anti-cancer activity as a single agent or in combination with CA-170, at the annual meeting of the Society for Immunotherapy of Cancer, in National Harbor, Maryland.

Upcoming Activities

Curis expects that it will make presentations at the following conferences through April 2018:

Cowen & Company 38th Annual Health Care Conference (March 12-14) in Boston

Conference Call Information

Curis management will host a conference call today, March 8, 2018, at 8:30 a.m. EST, to discuss these financial results, as well as provide a corporate update.

To access the live conference call, please dial (877) 870-4263 from the United States or (412) 317-0790 from other locations, shortly before 8:30 a.m. EST. 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 and commercialization of innovative and effective drug candidates for the treatment of human cancers, including CUDC-907, which is being investigated in clinical studies in patients with lymphomas 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 dual antagonists of PD1 and VISTA, including PDL1/VISTA antagonist CA-170, and oral small molecule dual antagonists of PD1 and TIM3, including PDL1/TIM3 antagonist CA-327, as well as to molecules designed to inhibit the IRAK4 kinase, including CA-4948. CA-170 is currently undergoing testing in a Phase 1 trial in patients with advanced solid tumors and lymphomas. CA-4948 is currently undergoing testing in a Phase 1 trial in patients with 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 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 CUDC-907, 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," "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 December 31,		Year ended December 31,	
	2017	2016	2017	2016
Revenues:				
Royalties	$ 3,144	$ 2,407	$ 9,849	$ 7,810
Research and development, net	118	(45)	49	(283)
Total revenues:	3,262	2,362	9,898	7,527
Operating expenses:				
Costs of royalty revenues	165	121	496	399
Research and development	6,919	9,159	45,096	31,590
In-process research and development	—	—	—	17,989
General and administrative	3,305	3,845	14,066	15,588
Total operating expenses	10,389	13,125	59,658	65,566
Net loss from operations	(7,127)	(10,763)	(49,760)	(58,039)
Other (expense) income	—	—	(104)	(1)
Interest income	181	80	513	406
Interest expense	(1,082)	(652)	(3,966)	(2,777)
Other expense, net	(901)	(572)	(3,557)	(2,372)
Net loss	(8,028)	(11,335)	(53,317)	(60,411)
Basic and diluted net loss per common share	$ (0.05)	$ (0.08)	$ (0.36)	$ (0.45)
Basic and diluted weighted average common shares outstanding	164,008,252	140,715,621	149,133,466	132,785,687

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	December 31, 2017	December 31, 2016
ASSETS		
Cash, cash equivalents and investments	$ 60,232	$ 44,485
Investments – restricted	153	153
Accounts receivable	3,073	2,459
Property and equipment, net	366	413
Goodwill	8,982	8,982
Other assets	992	1,260
Total assets	$ 73,798	$ 57,752
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 8,250	$ 8,626
Debt obligations, net	41,555	19,860
Total liabilities	49,805	28,486
Total stockholders' equity	23,993	29,266
Total liabilities and stockholders' equity	$ 73,798	$ 57,752

SOURCE Curis, Inc.

For further information: For More Information: James E. Dentzer, Chief Financial Officer & Chief Administrative Officer, Curis, Inc., 617-503-6500, jdentzer@curis.com ; Media Contact David Schull, Russo Partners, (212) 845-4271, david.schull@russopartnersllc.com

---

https://investors.curis.com/2018-03-08-Curis-Reports-Fourth-Quarter-and-Year-End-2017-Financial-Results