Curis Reports Second Quarter 2016 Financial Results

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

LEXINGTON, Mass., Aug. 04, 2016 (GLOBE NEWSWIRE) -- Curis, Inc. (NASDAQ:CRIS), a biotechnology company focused on the development and commercialization of innovative and effective drug candidates for the treatment of human cancers, today reported its financial results for the second quarter ended June 30, 2016.

"We are pleased that dosing of patients has started in the Phase 1 trial of CA-170, the first oral, small molecule immune checkpoint inhibitor targeting PD-L1 and VISTA pathways from our collaboration with Aurigene," said Ali Fattaey, Ph.D., Curis's President and CEO. "Additionally, the second immuno-oncology program in our Aurigene collaboration that is focused on oral small molecules that target PD-1 and TIM3 pathways continues to progress well, further supporting our strategy to address inhibitory immune checkpoints with oral small molecules."

Dr. Fattaey continued, "We continue to enroll patients in the Phase 2 trial of CUDC-907 in patients with relapsed/refractory diffuse large B cell lymphoma or DLBCL, to assess its efficacy specifically in patients with MYC—altered DLBCL and remain on track for data in 2017."

Second Quarter 2016 Financial Results

Curis reported a net loss of $11.3 million, or ($0.09) per share on both a basic and diluted basis for the second quarter of 2016, as compared to a net loss of $8.1 million, or ($0.06) per share on both a basic and diluted basis for the same period in 2015. Curis reported a net loss of $20.7 million or ($0.16) per share on both basic and diluted basis for the six months ended June 30, 2016, as compared to a net loss of $40.0 million, or ($0.34) per share on both basic and diluted basis for the same period in 2015. The net loss for the six months ended June 30, 2015 includes a non-cash in-process research and development charge of $24.3 million related to Curis's license agreement with Aurigene.

Revenues for the second quarter of 2016 were $1.7 million, as compared to $2.1 million for the same period in 2015. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®. Revenues for the six months ended June 30, 2016 were $3.4 million, as compared to $3.7 million for the same period in 2015.

Operating expenses were $12.4 million for the second quarter of 2016, as compared to $9.5 million for the same period in 2015.

Operating expenses for the six months ended June 30, 2016 were $22.9 million, as compared to $42.1 million for the same period in 2015, 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 second quarter of 2016 and 2015. Cost of royalty revenues for the six months ended June 30, 2016 and 2015 were $0.2 million for both periods.

In-Process Research and Development Expense. No in-process research and development expenses were recorded for the six months ended June 30, 2016 as compared to $24.3 million recorded during the same period in 2015 associated with the issuance of 17,120,131 shares of Curis common stock to Aurigene as partial consideration for the rights granted under the terms of the January 2015 collaboration agreement.

Research and Development Expenses. Research and development expenses were $8.8 million for the second quarter of 2016, as compared to $5.9 million for the same period in 2015. The increase was primarily due to increased direct spending related to clinical activities of CUDC-907 and programs under the Aurigene collaboration over the prior year period, including a $3.0 million milestone payment to Aurigene upon the U.S. Food and Drug Administration (FDA) acceptance of the CA-170 IND. Employee-related expenses increased over the prior year period primarily due to additional headcount to support the multiple programs. Research and development expenses were $15.7 million for the six months ended June 30, 2016 as compared to $10.7 million for the same period in 2015.

General and Administrative Expenses. General and administrative expenses remained unchanged at $3.4 million for the second quarter of 2016 as compared the second quarter of 2015. General and administrative expenses were $7.1 million for the six months ended June 30, 2016, as compared to $6.9 million for the same period in prior 2015.

Other expense, net was $0.6 million for the second quarter of 2016, as compared to $0.8 million for the same period in 2015. Other expense, net primarily consisted of $0.7 million and $0.8 million in interest expense for the quarters ended June 30, 2016 and 2015, respectively, related to the loan made by BioPharma-II (an investment fund managed by Pharmakon Advisors) to Curis Royalty (a wholly owned subsidiary of Curis). Other expense, net was $1.2 million and $1.6 million for the six months ended June 30, 2016 and 2015, respectively.

As of June 30, 2016, Curis's cash, cash equivalents, marketable securities and investments totaled $61.7 million and there were approximately 129.5 million shares of common stock outstanding.

Second Quarter Operational Highlights

Precision oncology (CUDC-907: HDAC / PI3K inhibitor program):

In June 2016, updated data from the Phase 1 trial of CUDC-907 in 75 patients with relapsed/refractory lymphoma or multiple myeloma were presented at the European Hematology Association's Annual Meeting. The updated assessment from a total of 31 of these patients with relapsed refractory DLBCL showed that among 21 response-evaluable patients

with DLBCL, objective responses were reported in 9 patients, including 3 patients with complete responses. Additionally, a retrospective post-hoc analysis showed that among 6 response-evaluable DLBCL patients whose tumors were characterized with MYC alterations, 5 experienced objective responses, including 3 patients with complete responses. All 5 patients with MYC altered disease who experienced objective responses also had alterations in BCL-2, including 2 patients with BCL-2 gene translocations.

In June 2016, Curis presented the CUDC-907 Phase 2 trials-in-progress poster at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting. The presentation included the Phase 2 study's design for investigating CUDC-907's efficacy in patients with relapsed/refractory DLBCL with MYC alterations.

Immuno-oncology (CA-170: PD-L1 / VISTA antagonist program; Aurigene collaboration):

In June 2016, the Company filed an Investigational New Drug (IND) application with the U.S. FDA to initiate the Phase 1 trial of CA-170 for once-daily oral treatment of patients with advanced solid tumors or lymphoma. The FDA accepted the Company's IND filing during the same month.

In June 2016, the Company initiated dosing of the first patient in the Phase 1 trial of CA-170.

Erivedge (partner: Roche/ Genentech):

In June 2016, Roche presented data from two trials of Erivedge at the ASCO Annual Meeting, highlighting that (1) the safety profile of Erivedge continues to be consistent with the previously reported safety profiles, and (2) intermittent dosing schedules may be an option for patients with multiple basal cell carcinomas to derive long term benefit from Erivedge treatment.

Upcoming Activities

Curis expects that it will make presentations at the following conferences through September 2016:

Baird's Global Healthcare Conference on Sept 8-9, 2016 in New York City

Conference Call Information

Curis management will host a conference call today, August 4, 2016, at 8:30 a.m. EDT, to discuss these financial results, as well as provide a corporate update.

To access the live conference call, please dial (877) 868-1829 from the United States or (253) 237-1135 from other locations, shortly before 8:30 a.m. EDT. The conference ID number is 56394008. 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 its lead candidate, CUDC-907 that is being investigated in clinical studies in patients with lymphomas and solid tumors. Curis is also engaged in a broad 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 the PD-1 and VISTA pathways, including PD-L1/VISTA antagonist CA-170, 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. 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, and are further developing Erivedge in other diseases including idiopathic pulmonary fibrosis and myelofibrosis. 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 Private Securities Litigation Reform Act of 1995, including without limitation statements regarding: the Company's expectations regarding the potential of the Aurigene discovery platform to generate multiple oral small drug candidates. 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, 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. 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. 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 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 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 June 30,		*Six months ended June 30,*	
	2016	*2015*	*2016*	*2015*
Revenues:				
Royalties	$ 1,842	$ 2,034	$ 3,586	$ 3,705
Research and development, net	(162)	49	(180)	36
Total revenues:	1,680	2,083	3,406	3,741
Operating expenses:				
Costs of royalty revenues	95	103	184	187
Research and development	8,822	5,938	15,650	10,657
In-process research and development	—	—	—	24,348
General and administrative	3,443	3,411	7,059	6,940
Total operating expenses	12,360	9,452	22,893	42,132
Net loss from operations	(10,680)	(7,369)	(19,487)	(38,391)
Interest income	119	84	224	124
Interest expense	(729)	(843)	(1,468)	(1,710)
Other expense, net	(610)	(759)	(1,244)	(1,586)
Net loss	$ (11,290)	$ (8,128)	$ (20,731)	$ (39,977)
Basic and diluted net loss per common share	$ (0.09)	$ (0.06)	$ (0.16)	$ (0.34)
Basic and diluted weighted average common shares outstanding	129,270,639	128,351,482	129,142,989	118,199,388

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	June 30, 2016	*December 31, 2015*
ASSETS		
Cash, cash equivalents and investments	$ 61,671	$ 82,191
Investments — restricted	153	153
Accounts receivable	1,869	2,106
Property and equipment, net	451	278
Goodwill	8,982	8,982
Other assets	978	1,255
Total assets	$ 74,104	$ 94,965
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	5,949	6,290
Debt obligations, net	21,968	24,165
Total liabilities	27,917	30,455
Total stockholders' equity	46,187	64,510
Total liabilities and stockholders' equity	$ 74,104	$ 94,965

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