

Curis Reports Second Quarter 2017 Financial Results

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

LEXINGTON, Mass., Aug. 03, 2017 (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, reported today its financial results for the second quarter ended June 30, 2017.

Curis also reported today data from the interim analysis of the Phase 2 trial of CUDC-907 in patients with MYC-altered DLBCL. Of the 36 evaluable patients with MYC-altered DLBCL in the interim analysis, 7 patients experienced confirmed durable objective responses (19.4% ORR), including 3 with complete responses. In addition, and consistent with the original hypothesis, all 7 responders in the Phase 2 study had MYC-altered disease, while no objective responses were observed in 12 patients with MYC-negative disease status.

"The ability of CUDC-907 treatment to result in durable complete responses, and the continued correlation of this benefit selectively in patients with MYC-altered disease, is encouraging for the continued development of CUDC-907," said Ali Fattaey, President and CEO. "While we believe the results from this Phase 2 trial are insufficient to serve as the basis of a request for accelerated approval of CUDC-907, we are evaluating alternative designs for a separate registration-enabling trial to demonstrate CUDC-907's benefit for patients with MYC-altered DLBCL."

"The reported response rate is impressive, especially in this population of patients with relapsed/refractory MYC-altered lymphomas who rarely respond to salvage therapies," said Dr. Daniel J. Landsburg, Assistant Professor of Clinical Medicine at the Abramson Cancer Center at the Hospital of the University of Pennsylvania. "I believe this agent warrants continued investigation."

Second Quarter 2017 Financial Results

Curis reported a net loss of \$14.1 million, or \$0.10 per share, on both a basic and diluted basis for the second quarter of 2017, as compared to a net loss of \$11.3 million, or \$0.09 per share, on both a basic and diluted basis for the same period in 2016. Curis reported a net loss of \$29.8 million, or \$0.21 per share, on both a basic and diluted basis for the six months ended June 30, 2017, as compared to a net loss of \$20.7 million, or \$0.16 per share on both a basic and diluted basis for the same period in 2016.

Revenues for the second quarter of 2017 were \$2.1 million, as compared to \$1.7 million for the same period in 2016. Revenues for the six months ended June 30, 2017 were \$4.2 million, as compared to \$3.4 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®.

Operating expenses were \$15.2 million for the second quarter of 2017, as compared to \$12.4 million for the same period in 2016. Operating expenses for the six months ended June 30, 2017 were \$32.4 million, as compared to \$22.9 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 \$0.1 million for both the second quarter of 2017 and 2016. Cost of royalty revenues for the six months ended June 30, 2017 and 2016 were \$0.2 million for both periods.

Research and Development Expenses. Research and development expenses were \$11.3 million for the second quarter of 2017, as compared to \$8.8 million for the same period in 2016. The increase was primarily due to increased direct spending related to clinical activities of CUDC-907 and CA-170 and increased employee-related expenses primarily due to additional headcount to support the multiple programs. Research and development expenses were \$24.8 million for the six months ended June 30, 2017 as compared to \$15.7 million for the same period in 2016.

General and Administrative Expenses. General and administrative expenses were \$3.8 million for the second quarter of 2017 as compared to \$3.4 million for the same period in 2016. The increase in general and administrative expenses was driven primarily by higher personnel costs and stock-based compensation expense due to increased headcount. General and administrative expenses were \$7.4 million for the six months ended June 30, 2017, as compared to \$7.1 million for the same period in prior 2016.

Other expense, net was \$1.0 million for the second quarter of 2017, as compared to \$0.6 million for the same period in 2016. Other expense, net primarily consisted of interest expense related to Curis Royalty's (a wholly owned subsidiary of Curis) debt obligations. Other expense, net was \$1.7 million and \$1.2 million for the six months ended June 30, 2017 and 2016, respectively.

As of June 30, 2017, Curis's cash, cash equivalents, marketable securities and investments totaled \$51.0 million and there were approximately 143.9 million shares of common stock outstanding. On a fully-diluted basis, which includes 18.6 million options, there were 162.5 million shares outstanding.

Recent Operational Highlights

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

The following summarizes the CUDC-907 Phase 1 trial results and Phase 2 interim analysis:

<http://www.globenewswire.com/NewsRoom/AttachmentNg/00057193-8320-464f-ad49-fb2f9a7263ce>

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

In May 2017, Curis presented the CA-170 Phase 1 trials-in-progress poster at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting.

Upcoming Activities

Curis expects that it will make presentations at the following conferences through September 2017:

CA-170 poster presentation at the European Society for Medical Oncology (ESMO) Conference (Sept. 8-12, 2017) in Madrid.

Conference Call Information

Curis management will host a conference call today, August 3, 2017, at 8:30 a.m. EDT to discuss these financial results and 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 61970970. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section.

About Curis

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 development candidate, CUDC-907 which 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 PD1 and VISTA pathways, including PDL1/VISTA antagonist CA-170, and oral small molecule antagonists of the PD1 and TIM3 pathways, 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. 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 myelofibrosis. 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.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(In thousands, except share and per share data)

	<i>Three months ended June 30,</i>		<i>Six months ended June 30,</i>	
	<i>2017</i>	<i>2016</i>	<i>2017</i>	<i>2016</i>
Revenues:				
Royalties	\$ 2,102	\$ 1,842	\$ 4,294	\$ 3,586
Research and development, net	(41)	(162)	(102)	(180)
Total revenues:	<u>2,061</u>	<u>1,680</u>	<u>4,192</u>	<u>3,406</u>
Operating expenses:				
Costs of royalty revenues	96	95	207	184
Research and development	11,255	8,822	24,795	15,650
General and administrative	3,819	3,443	7,351	7,059
Total operating expenses	<u>15,170</u>	<u>12,360</u>	<u>32,353</u>	<u>22,893</u>
Net loss from operations	<u>(13,109)</u>	<u>(10,680)</u>	<u>(28,161)</u>	<u>(19,487)</u>
Other (expense) income	-	-	(104)	-
Interest income	138	119	208	224
Interest expense	(1,119)	(729)	(1,775)	(1,468)
Other expense, net	(981)	(610)	(1,671)	(1,244)
Net loss	<u>(14,090)</u>	<u>(11,290)</u>	<u>(29,832)</u>	<u>(20,731)</u>
Basic and diluted net loss per common share	<u>\$ (0.10)</u>	<u>\$ (0.09)</u>	<u>\$ (0.21)</u>	<u>\$ (0.16)</u>
Basic and diluted weighted average common shares outstanding	<u>143,786,705</u>	<u>129,270,639</u>	<u>142,904,144</u>	<u>129,142,989</u>

CURIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands)

	<i>June 30, 2017</i>	<i>December 31, 2016</i>
ASSETS		
Cash, cash equivalents and investments	\$ 51,042	\$ 44,485
Investments — restricted	153	153
Accounts receivable	2,231	2,459
Property and equipment, net	426	413
Goodwill	8,982	8,982
Prepaid expenses and other assets	961	1,260
Total assets	<u>\$ 63,795</u>	<u>\$ 57,752</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	\$ 10,682	\$ 8,626
Debt obligations, net	43,885	19,860
Total liabilities	<u>54,567</u>	<u>28,486</u>
Total stockholders' equity	<u>9,228</u>	<u>29,266</u>
Total liabilities and stockholders' equity	<u>\$ 63,795</u>	<u>\$ 57,752</u>

For More Information:

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<https://investors.curis.com/Curis-Reports-Second-Quarter-2017-Financial-Results>